NLM ClinicalTrials.gov Public Meeting, April 25, 2023 – PRS Breakout Session Transcript

PRS Moderator, Stacey Arnold, NLM: Alright. It looks like we are now at 2:00 PM. So I just want to welcome everyone to the PRS Beta breakout room.

My name is Stacey Arnold, and I'm a results team subject matter expert. I contribute to the modernization of both the PRS database and the public website. Today we'll be hearing from Carrie Dykes, who is a PRS administrator with the University of Rochester and has been serving as a Board of Regents member with NLM advising the modernization efforts.

We'll also be hearing from our PRS Beta modernization product owner, Nachiket Dharker. Carrie and Nachiket will be presenting in a conversational manner with Carrie speaking to highlights of the PRS Beta and opportunities for improvement, and Nachiket stepping in to address those opportunities point by point. I will break in with any pertinent questions along the way. So, if you have questions related to the content that is presented, please address them to everyone in the chat. We'll also field as many additional questions as possible at the end.

If you have any technical issues, please direct them to the tech support person via the chat.

The other breakout room is being recorded as Anna mentioned, and that recording and slides from that presentation will be shared on the ClinicalTrials.gov modernization page after the meeting.

With that I'll now turn things over to Carrie to get us started. Carrie, please take it away.

PRS Administrator, Carrie Dykes, University of Rochester: Thank you, Stacey. Hi, everyone! I'm Carrie Dykes. I'm from the University of Rochester, and work in our Clinical and Translational Science Institute. I am also the PRS administrator for our institution, and as an administrator I've gone in and I've looked at the PRS Beta homepage, and I've looked gone into the PRS Test to look at the Record Page and tried them out to see how they worked and what I really liked about them, and some issues that I still had, that I hope will be improved in the future. So I'm just gonna go through some of those things now.

So first, one of the good things about the new home page in PRS Beta is the ability to save a view of the records. So as an administrator, when you're working on the home page, often you want to be able to see different columns of data in different ways for different purposes. But in the current classic system, you can't save those views. You have to kind of regenerate them each time. But now, you can see that there's a place to save views, and I created my own Problem Records view, for instance, as an example. So, this has been a very nice improvement.

Another nice thing about the home page is that, like in the classic system, you can do a search for all of the columns of data that are available, but you can also search a specific column like just the NCT number, or just the Brief Title, which is helpful when you're trying to find a

particular record amongst the list of sometimes thousands of records. So, this added feature does make it easier to find some records in certain situations.

And then in the Protocol Registration record in PRS Test, one of the great things is the change in navigation. So it used to be in the classic system, you would have to click in and out, back and forth, between each section of the study record to view it, and then go back to look at the next section of the study record. But now you have that all lined up on the left-hand side, so you can just click on each one as you work down the record and fill in or edit your study information.

The next thing that's been really helpful in the new system are these info buttons. So in the classic system, you used to have to go to the top of the record and find the list of definitions for each data element and then scroll through that list to find the one that you needed, for Record Verification date for instance.

Now, they've broken up all of that information, so that it's assigned or linked to each data element, and so you can just click the info button, which is very intuitive like most websites, and you can see on the right-hand side, the data element definition and additional information. And so you don't have to look through a long document of data elements to fill in this whole section. You can see one each, one by one.

Okay, so those are some of the things that I thought were great improvements and will really be helpful as an administrator. There are also a few things that I think might be helpful to me as an administrator.

And so the first one is, if the study record has an NCT number, I always use that number whenever I communicate with the Record Owners, or the responsible parties for the record. And so here, in the current system, the way it works is they put the Study Identifier in the subject line. I would like to see the NCT number in the subject line. So that's one thing that would be helpful for me, not to have to go in and add that each time I send an email to the Record Owner from the home page.

Some other email template things that would be helpful that may be possible or may not be possible as I've indicated here in yellow and red. It would be helpful in the future if the template language could be customized for each institution. As administrators, we all have different ways of communicating with our Record Owners and responsible parties and so having a way for us to actually customize our email language would be helpful.

Also, at my institution, whenever I email about a record, I always email both the responsible party and the Record Owner. That's just our policy here. And it would be helpful to be able to do that from the home page. You can email each one separately, but you can't email both of them together very easily. So that would be another thing that would be helpful.

And Nachiket, I'm gonna hand it over to you, for a response.

PRS Beta Product Owner - Nachiket Dharker, NLM: First of all, thanks Carrie, for taking time to play around with the PRS Beta, and also thanks for going over some of the features that you liked in the PRS Beta.

We are very happy to know that you like these features, and you thought that they are big improvements, and we'll continue to hopefully make these kind of increments, improvements throughout this project. We also appreciate you noting some of the issues in the current PRS Beta, and providing recommendations. I think this is very helpful.

Some of the issues that you noted that we are already aware of, and we are currently working to resolve them. And other things are that you noted are, you know as I said, great recommendations that we will take back to our team for further discussion and then basically evaluate based on the different user group how we can implement those, and if there are some, you know, technical difficulties that we may run into, etc.

So regarding your first. You know the issue that you noted about NCT number, or you know, including the NCT number on the subject line. I think again it's a great suggestion. We can certainly explore displaying NCTs on the email subject line, although we will continue to display the unique protocol IDs in the subject line too, because all records would have a unique protocol ID but the same is not always true for the NCT number. And NCT numbers are assigned only in cases, or only to those registration records, that are posted on the public site for the first time, and since our users may have in their record list some records that do not meet these, this criteria-that they are not posted on the public site- in those cases there will not be any NCT for those records. But I think it's a great suggestion that maybe we can include both these numbers on the subject line.

Regarding creating emails, email templates for, or allowing users to define their own templates, again, this is a very interesting recommendation, and we will definitely explore this. This is something that we will need to explore further and take it to our team for further discussions, because the way I understand it, is in order for us to provide that capability, you know, we will have to give a way to our users to be able to create these templates and save them within the PRS, so that they can use them for correspondence, and currently we do not have that kind of functionality. But we can certainly explore that.

In the meantime, users what they will need to do now, is to get the same function or the same functionality is to create their own templates, but save them outside of the PRS, which I'm sure many of you are doing.

As far as allowing multiple addresses to be emailed at once, this is again a great recommendation. We can certainly explore how, you know, we can do that, and you know, explore the potential to select multiple email addresses in the To: or CC: or BCC: fields of the email. And I think what jumps to my mind is we can potentially leverage the access list for the record. You know, the Record Summary page has a link to the access list that you know a user

or the record owner assigns, or you know checks whoever they want to provide access to the record, and we can perhaps pull those names to complete this request.

So definitely some good points to explore.

And back to you, Carrie.

PRS Administrator, Carrie Dykes, University of Rochester: Yeah, thank you Nachiket. That's good to hear.

Okay. So some other things that I identified as I was working through the record in the PRS Test was several places where asterisks are indicated, and this means that the field is required to be completed in order to go through the records. So, and this is true in the classic system, and has been transferred over to the new system in the Beta. So, however, some of things like middle initials, or extensions- phone extensions- are not necessarily pieces of data I would use or have. So, for instance, at the University of Rochester, we don't have extensions. We just have regular phone numbers for everyone. So this becomes a problem when you're trying to complete the record, to have to enter data that you don't necessarily need to.

Another thing is, there's a new way in which the errors are now shown for a record, as you're looking at it and working through filling it out. It's the list of errors show at the top, which is really helpful. However, like most forms that you complete in a web environment, it would be helpful to have the fields that are, that have errors highlighted within the records, so that they're easier to find.

Another thing that's a little confusing, is when you're completing a record for the first time, errors will appear in the list for sections of the record that are downstream that you have yet to complete. And when I was testing the system, it was a little confusing to me, but would be helpful if those errors didn't necessarily occur or appear until you completed those downstream data elements.

Okay. Back to you Nachiket.

PRS Beta Product Owner - Nachiket Dharker, NLM: Yeah. Thanks, Carrie. Yeah. Again, both these are great observations in the PRS Test System, and we are aware of these issues.

So regarding the first one, you know, the asterisks are the requirement symbols, you know, potentially wrongly placed, incorrectly placed on some of the fields.

We are working to review all the requirement symbols and all the content, onscreen content currently, and wherever they are inconsistent with the data element definitions, we will go and correct these to what they should be and to be consistent with the requirements. The goal is to label, as I said, all the fields according to individual requirements. And we hope to resolve this as much as possible of this issue by our May release to the PRS Production site. However,

once we release the updates to the PRS Production site in May, if you still see these kind of issues with the requirement symbols, please use the feedback button, the button on the bottom right of the screen, to notify us.

And this is also a good, great place for me to take the opportunity to clarify that we have not changed any of the requirements as part of the modernization. We are simply modernizing the user interface and the system. All the requirements still remain the same.

As far as the error messages are concerned, we acknowledge that currently in the new system they are all placed on top of the screen, And that is, you know I realize that users, it's not the best user experience, and the classic system currently does, you know, place errors next to every field or below every line. And so we are working towards this goal also. In our future release, not this May, but in our future release, we definitely hope that we will be able to implement this — that errors will be placed at the field level, or we can provide additional context to help our users better understand the context to the error so they can go back and change data in that field.

So, yeah, we are on it.

PRS Administrator, Carrie Dykes, University of Rochester: Alright! Good to know that the work, you know, all the playing around I did found some helpful things.

PRS Beta Product Owner - Nachiket Dharker, NLM: Absolutely.

PRS Administrator, Carrie Dykes, University of Rochester: Okay, and then another thing I noticed is when you're registering a record for the first time, at the bottom of the screen, as you complete each of these sections on the left, there's a Save Edits button.

Is that intuitive as an action button? When you're creating a record for the first time, and all of the fields are blank. So something like Next, Save, or Continue, I think are more intuitive. It makes sense to have this when you're going back into a record that you've already released, and you need to go back and save edits, that you've changed, maybe the year or the month. But for the first time filling it out, it was kind of confusing why that terminology was used.

And then the other thing that would be helpful is, when you are looking for people, the names of users, to populate different fields in the record. The user list is listed in alphabetical order by first name, which isn't really the easiest way to find people. And for some institutions who have thousands and thousands of users, it could, you know, it can be hard to find people. So it would be nice if the list would be searchable, and it would be nice if the users could be in the system, in these lists, by last name rather than first name. So that was another thing that would be helpful for me.

PRS Beta Product Owner - Nachiket Dharker, NLM: Yeah. Thanks. Carrie, again. Great observations and good recommendations. Thanks for that.

Regarding the Save Edits button that you showed, that is definitely something, we realize that we can, you know, it makes sense. I think we can change it to just say Save, because it that may work best for, you know, the first-time users as well as people who want to come in and make revisions. So that's where I think we will, that's how we will change the name of that button.

And then regarding alphabetizing the list in the Sponsor and Collaborators field, the list for user names, we will definitely explore the use of this option. We do have a, you know, search field there that allows you to search. But alphabetizing is going to be more tricky in this case, just because it depends on how the users enter this information, their first name and last name, when they are creating the accounts.

So currently in the classic system, there is a single field for the name when a user creates an account. And it totally depends on what format users enter the name, and the system just takes that format. And that gets populated in this list, and it may not be, that format may not be always first name, last name. It may be just one name. And so we will have to find a way to pull in more information, and if we do in the future, collect that kind of information, my assumption is, you know, at the end of modernization, we will move to a single sign-on or a federated login. Then we will be able, at that point of time I guess, it will be much easier for us to pull in that information and provide this functionality.

PRS Moderator, Stacey Arnold, NLM: Hey, Nachiket, it's Stacey. I'm just breaking in to say that we're getting a lot of support in the chat for a better search for this feature, and in addition, a request for similar searchable feature for disabling user accounts. So I just wanted to let you know that this point of Carrie's is a popular one.

PRS Beta Product Owner - Nachiket Dharker, NLM: Great. Thanks, Stacey, for chiming in. Yea, definitely, and again, if these features are important for you and you have these kind of recommendations, again, we I would strongly encourage you to continue using the feedback button and let us know, so that you know we can, as you heard in the earlier session, we read and review each and every piece of comment. So that will be useful.

So I think we are done with this part, Stacey, so it's, I would pass it to you to take the next polling question.

PRS Moderator, Stacey Arnold, NLM: Certainly. Okay. So I've been trying to monitor the chat and answer some questions as we go along. And I just wanted to mention, I think we've already broken in to say that we'll be taking questions at the end, and we'll try to get to as many as we can, and I apologize in advance, if we're not able to get to all of the questions. But we did want to ask some general questions of the group, and we're going to do them as polling questions. But unlike the main room, it won't be possible for a popup to appear where people can actually enter their answers. Instead, we would ask that you enter your answers in the chat.

We really do value the feedback that we can get from these polling questions and we'll take them into consideration as we continue to develop the PRS Beta site. So we will be copying the chat and tallying the responses. So, even though we won't be able to share the responses with you at this time, we will take the responses into consideration, and really use them to inform our efforts.

So our first question is about the Record Summary page, and we have a couple of options for producing draft receipts of a record, either in PDF, or RTF Rich Text Format. And we want to know just how much these features are used. If one or both are pretty popular among our users. I don't think I'm able to advance, so Nachiket maybe if you can advance the slide.

And so this is just a popup of what the PDF version looks like for those of you who aren't familiar, or if you are familiar, this is gonna look like something you see a lot of the time.

Okay. Next slide please.

So I see we're already getting a lot of responses. Thank you. And we'll take those into consideration as well. I mean, if you want to give a formal response to the question, and the version, in the manner of A, B, C, or D, our question is: Do you use these?

And the answer is, A are, the options are A: Yes, I use both formats. B: I use the PDF format, C: I use only the RTF format, or D: I don't use this option. And I see the answers coming in fast and furious. So thank you so much to everyone who is responding. So far I can kind of track the answers and I think the PDF version is pretty popular.

So we really appreciate that feedback. And we do have a person saying, please don't get rid of the RTF. That is a valuable comment as well. So, thank you so much. You can continue.

I think it's slowing down. So, I think we're ready to move on to the next polling question if everyone's on board with that, so that we can get to general questions that folks had at the end.

Okay, so, our second question has to do with the Contacts and Locations module in the classic system. And so there are a couple of links there. One is Copy locations, and the other is Set multiple Locations' Site Recruitment Status. And again, we want to know if you're using these features, how important they are to you and we will have a question if you want to wait to formally choose one of the options, but if you have additional feedback, you know we are happy to see that in the chat as well.

Okay, next slide.

And so, just as a reminder, this is, or maybe as an introduction, this is what the Copy Locations window looks like. And so you can use the side here to check off boxes for locations that you

might have already entered into your organization's account information and that can be copied over into any record. And so these are generally populated from former record entries.

And next slide.

And then this is the way that in the classic system we can add the site Recruitment Status for multiple locations. So in the first step you would select, which Recruitment Status might apply to one or more, and then in the second step you can select as many locations as fit that bill, and click save to add that information.

So the question is, which of these features do you use? A: Both. I Copy Locations and I set multiple Locations' Site Recruitment Status, B: I only use the Copy Locations feature, C, I only set multiple Locations' Site Recruitment Status, or D: I don't use either of these features.

And again I see a lot of responses coming in. This time it's looking like, I don't use either, is the most popular. But again, if you have a passionate need to continue these features, or access to these features do let us know.

Alright! I'm seeing the answers start to slow down so.... Leave it flexible, I ask, on behalf of newer staff. Thank you for that feedback.

Okay. So I think now, we can probably move on to some of the questions that we have been getting in the chat.

And so I'm gonna try to start pulling those up.

And I think Nachiket you're going to be in the hot seat when it comes to trying to answer these, so hopefully we can get clarification on anywhere it isn't entirely clear what they're asking, or, you know, get their feedback if for some reason we aren't on point in answering.

But our first question is, we can currently only view and export 250 records. Are you planning to expand this limit in the future?

PRS Beta Product Owner - Nachiket Dharker, NLM: Oh, so this question is specific to the Export feature?

PRS Moderator, Stacey Arnold, NLM: I think the View feature as well. It's View and Export.

PRS Beta Product Owner - Nachiket Dharker, NLM: Oh, View, right. So regarding the View feature, definitely yeah. I mean, when we have, we already on the PRS Test, we have set the limit now to 1,000 records. So you know, we had in the past some performances issues, but we have solved, resolved those, and oh, in May, when this we will update, or push the updates to the production site, you will notice that now the new limit is 1,000 records for viewing on the record list. We are moving towards and actively working on having no limit.

Just recognizing that, you know, the number of people who have more than 1,000 records as a percentage of our user base is low. So, we are right now we want to ensure that most of the users who have, you know, the number of records in their list below 1,000, are, you know, getting the optimal performance. But, as I said, we are anticipating that soon, in the like current like future versions, we are going to remove that limit also.

Regarding Export, I don't think we have any change in the plan. I think, whatever limit we have currently is going to be set for the exporting also. Stacey, do you remember? Let's say you go to 1,000, are we going to allow 1,000 records to be exported? Is that...

PRS Moderator, Stacey Arnold, NLM: I believe that's probably the case, yeah.

PRS Beta Product Owner - Nachiket Dharker, NLM: Yeah, but I think the limit will basically translate, you know, be for on both sides.

PRS Moderator, Stacey Arnold, NLM: Okay, great. So let's move on to the next question, because we do have a fair number here.

So the next question, that we can address here is, will we have a problem records tab like the classic site? Or is the drop-down checkbox the only selection for finding problem records?

PRS Beta Product Owner - Nachiket Dharker, NLM: Sorry Stacey, I lost your audio. I mean I couldn't hear. I think it was an issue on my end. Can you repeat the question?

PRS Moderator, Stacey Arnold, NLM: Oh, certainly! So it's a question about whether there will be a tab for problem records, as there is in the classic site, or if the drop-down checkboxes will be the only means of access to get information about problem records?

PRS Beta Product Owner - Nachiket Dharker, NLM: Right, so for the problem records, we, you know, as some of you would have noticed, we are still, you know, we did provide administrative tools when we released the Portfolio Management, but we still have some work left. So at this point I'm not sure we will continue supporting the checkbox, but we will, I know that feature is important to our users, so we will support that in some form.

We are not going to take away that feature, as I said because we realize it is important for our users.

PRS Administrator, Carrie Dykes, University of Rochester: And I also wanted to point out that you create a save view that's just your problem records, and, you know, that saves. You can just go back to it every time you want to see your own list.

PRS Moderator, Stacey Arnold, NLM: That's a great point, thank you, Carrie. So I just want to step back to that 1,000 record issue again. I think there's some concern about when PRS Beta

becomes primary, if that will still be an issue at that time. Nachiket if you can speak to that quickly.

PRS Beta Product Owner - Nachiket Dharker, NLM: Yeah, no, we definitely want to, you know, allow as many records that you have in your folder or your account to be displayed, so as I said we will, even if there are 5% of the users have 1,000 plus records, but we will, you know, support that moving forward. As I said, we are just kind of you know, working to make our system more efficient, the Beta site, or more, you know, the performance, increase the performance. And as soon as we feel we've tested out all these use cases, we will roll it out, and in the future we will support all records that you have in your account. They should be displayed ideally.

So no. This will not happen once the Beta becomes primary, this should be resolved.

PRS Moderator, Stacey Arnold, NLM: Okay, and so another question. We've been getting some questions about some bugs that we've been having with the Problems view. And so one, actually this is from Carrie I think.

Currently, every record in the Beta system is on the Problems list, because it says they are missing FDAAA information. Will that be fixed?

PRS Beta Product Owner - Nachiket Dharker, NLM: Right, so my guess in PRS Test system now. So we did I think in the last couple of weeks we did resolve all of your, we were focusing really on Protocol Registration, but we did resolve some of the, you know, some of the pending bugs that were reported to us or we had observed, and to do with the, you know, the problems records and you know, data being inaccurately displayed in the columns. And those should be reflected on the test system, but again the hope is when we release in May these will be updated to the PRS Production site. And hey, no, we definitely want to resolve this.

So, if not all the bugs are resolved by May, we definitely will, you know. We are working on these actively as we, you know, started, or we find bugs in the protocol new screens that we building, we are also prioritizing. You know, we have to kind of balance the prioritization between resolving the previous bugs and the current bugs, or new bugs. But we are getting to all. It's all on our list, and we are getting to them. We just have to prioritize these issues that we are facing. But yeah they will be resolved.

PRS Moderator, Stacey Arnold, NLM: Could you... Sorry, Nachiket. We had a question related to bugs just about whether the bugs that are on the PRS Beta side of things might affect the records on the classic site. And I was wondering if you could speak to that.

PRS Beta Product Owner - Nachiket Dharker, NLM: That's a great question, and no, it shouldn't. So what, you know, we have the same, the two applications are sharing the same database, but for example if we have some issue in the Beta site, for example there is a validation that you were supposed to see and but you are not seeing for example, let's say in protocol

registration. When you go to the classic site, that's what you are going to still, ah, you will need to use that to submit the record. You will see the actual errors or to see that validation on the classic site. So we are not touching the classic site, right? So only building the new site as a separate application.

So the validations and how they should happen, are the gold standard, as you can call the classic site, is still performing the way it has to. And the idea is, and that's why I think I in my previous, in my presentation in the main room, I emphasized that if you are seeing like differences between classic system, and how the information is displayed on the Beta site, or if you are seeing any issues with the validations or some other bugs related to that, please use the feedback button to inform us. We can do as much of testing from our side, but we really depend on, you know, to cover all the use cases, we really depend on our users.

And we really want to make you be comfortable, you know, once we release the Protocol Registration, we want to make sure that we, you know, resolve as many issues by your feedback and by our testing and that until that point we will not, you know, provide the opportunity for the user to summit the record in the new system. We want to ensure that we, you know, we resolve, you know the Beta Protocol Registration data entry screens on the Beta site work to our satisfaction, before we allow people to do that.

So long answer. But it is important question. So I want to kind of give a more detail, like a detailed answer, that if we are missing something on Beta, the classic system is still, you know, pointing those things out.

PRS Moderator, Stacey Arnold, NLM: And Nachiket we did get some feedback that there seems to be some crossover from bugs in Beta. I think if people are sensing that or experiencing that, the way to try to resolve it is to write into register@clinicaltrials.gov or to use the feedback button to let us know, so that we can investigate specifically what it is that you are observing and try to troubleshoot it, if it is indeed a crossover of anything from the Beta to the classic system.

Okay, so a...

PRS Beta Product Owner - Nachiket Dharker, NLM: Oh, Stacey, I would just say here that, again a great point, please please write to us, because we will be interested. It's just that, you know, again as I said earlier, if you can provide any context. You can of course tell us what the problem is, but if you can provide any context like if you can give us any protocol ID, or if it is happening with specific records, then point to those records in your folder, so that, you know, we can take a look, that will give us more, a better idea of how to point the problem, and we can resolve the problem. Thanks, go ahead.

PRS Moderator, Stacey Arnold, NLM: I think we're also getting feedback about errors being assigned in Beta. These are not errors, this is a bug. So if you see an error in Beta that isn't carried over into classic, that isn't trumping the information that's in classic. The information in

classic is the information to go by at the moment until we resolve issues with error bugs. I'm getting a lot of feedback in the chat about that, but I think that's something to try to make clear to everybody. You're seeing in Beta is not, is not trumping, of what is what you know to be the case in the classic system.

PRS Beta Product Owner - Nachiket Dharker, NLM: And that is why it is the Beta system. The primary site is still the classic system. We are just, you know, building and really, Protocol Registration is really the first set of screens that involve data entry. And as you know, there is a complex set of validations involved so and that's why we want to test. As I've said we are continuing to test. But again, the classic system really is still the go to system.

PRS Moderator, Stacey Arnold, NLM: Okay. So we've gotten a couple of questions about Eligibility Criteria. And so one of these, I think there are generally about, you know, ways to make it easier for those who are entering information in the system. And so one question is, are there plans to auto fill Eligibility Criteria from house records when trial coordinators upload a new one? And in general, what plans does the modernization team have to save coordinators time on creating new records?

Nachiket. Can you speak to this at all?

PRS Beta Product Owner - Nachiket Dharker, NLM: If I'm understanding the question correctly, and Stacey, feel free to chime in if you have a better understanding. No, you know, we, on the modernized Protocol data entry screen, currently in this round of modernization, we are not changing the Eligibility Criteria, how you enter the data, and how that works. We are keeping that functionality the same.

Moving forward, I know we have received a lot of feedback in the past when we collected the RFI feedback on the Eligibility section. But we realized that it really needs you know more thorough, I think there have been requests on standardized language, inclusion of standardized language for eligibility, and other kind of feedback, and we think that we need, you know, once we have the basic modernized system ready, and we enter the stage of continuous improvement, that is when we will be able to do more research and accommodate some of these requests.

But, Stacey, I don't, if you have a better understanding of the question, please feel free to answer or add to what I said.

PRS Moderator, Stacey Arnold, NLM: I do not. I'm sorry I was out there doing a multi-task, and getting the next question primed for you so apologies, Nachiket. So hopefully, just let us know in the chat if that didn't answer the eligibility questions that folks have, and we'll try to readdress that question.

And so, I've seen this question a couple times. Are you planning to automate Record Verification date on uploading the study record? I think one user indicated that it seems like a simple quality of life improvement.

Nachiket, what do you think?

PRS Beta Product Owner - Nachiket Dharker, NLM: Yeah, that's interesting. And definitely, it seems like a very easy thing to automate, however, just right now, you know, we have no plans to do that and I think I don't want, you know, to quote something inaccurate here, but my understanding is like organizations really that is more of a check within the organizations to, you know, and some organizations do that, they require, you know, their administrators or their users to periodically go and verify that the information is updated on a regular basis, and so that kind of, you know, if you automate that once somebody logs in, that kind of I think defeats the purpose.

So I think that's more of a conscious choice of, hey somebody goes in verifies that there are no updates needed to the record, or they make the updates, and sign off. So I, that's how I understand that functionality. But again, Stacey or Amanda or other moderators, if you have a better understanding, please chime in.

PRS Moderator, Stacey Arnold, NLM: Yeah, I think as long as it didn't automatically update, and the user still had to acknowledge that the information was up to date as of that date. There might be some middle road to strike there, or middle ground to strike there.

And so I just wanted to mention that we've gotten a comment just back to eligibility really quickly, that standardized language would be useful for participants searching on the public site for potential studies. I don't know how much we we can do to sort of help fill in eligibility criteria from a list of options but we do get that feedback pretty frequently. So we just wanted to acknowledge that we've heard that request.

Okay? So I think another question is about emails to the PI record owner and anyone in the record access list and potentially adding that record access list to our planning report as a column, just in case there are additional names there that would be useful, that don't have those other defined roles. Nachiket, what do you think about that?

PRS Beta Product Owner - Nachiket Dharker, NLM: Yeah, I mean, I think that's a great, that's a good recommendation. We can certainly explore that.

Right, that's my immediate thought. I mean what we will do with any of these kind of recommendations, as I said, while, you know, based on what Carrie observed, some of these things we can easily point that we can do, we cannot do, but for some of the, like this kind of request, we definitely have to take it to our team and explore more.

But thanks. We will definitely consider it.

PRS Moderator, Stacey Arnold, NLM: Okay. So I am kinda slowing down on. I think I've seen a lot of questions come through, and I apologize if we've missed any. So far a lot of informative feedback from folks about things that we've been discussing along the way.

So I think we've touched on a lot of things, Nachiket.

PRS Beta Product Owner - Nachiket Dharker, NLM: Yeah, I was just saying that, you know, reminding that we do have a record, we will have a record of this chat. So we will get even if we were not able to answer any question at this time, if we were not able to do that. We will go back and review all this communication on whatever comments you provided in the chat, the polling responses, and so we will review each and every comment. So don't think that we are not, you know, that we didn't pay attention to any of these comments. We will absolutely do that.

And again feel free to write to us either using the feedback button or at register@clinicaltrials.gov. And we'll be happy to hear from you.

PRS Moderator, Stacey Arnold, NLM: Okay, and that kind of helps us touch on some of the general questions that we were getting ahead of the session today. So one, for example is, I gave feedback about the PRS. How was it, or will it be used to improve the site?

PRS Beta Product Owner - Nachiket Dharker, NLM: Yeah, so and so this is something that I think Catherine in her presentation touched upon, and Wendy touched upon, that, you know, what we do is when you use the feedback button to provide us the feedback, we have a triage team, who, they regularly go into their emails or wherever this information is collected. They review each and every feedback. We log it and document it by date, and then we basically, you know, review those, and whenever needed we review them with our team members. If we need developers input on some technical aspects, we discuss with the developers. If it is a design related question, like the button or you don't like aspects of the UI, we take it to our design team. And then, basically, we have to prioritize all of how we are able to act on that. So this is on a broad level our system and the process we use.

PRS Moderator, Stacey Arnold, NLM: Okay! And I think we have time for one more question. And one did come into the chat that I think, is probably very useful to folks, so if we can get it in on time.

Are there any changes to the way PRS administrators will be able to track when results are due for NIH funded clinical trials that aren't ACTs?

PRS Beta Product Owner - Nachiket Dharker, NLM: So we are, you know, on our roadmap there is, you know, we are working on notifications and, you know, to give, provide better, you know, tracking, and allowing our users to get a pre-notification emails, and you know, flags on when the records are due, and when certain kinds of records are present in their record list. So okay,

we will have to explore this further. I cannot promise at this point to what capacity we will support these kind of requests, but again, just send this in again as a feedback, and we will explore it further.

PRS Moderator, Stacey Arnold, NLM: Okay. Well, I'm trying to get it as many of these as we can, and hopefully no one's gonna miss out by trying to leave the breakout room before we get pushed out, that...

PRS Beta Product Owner - Nachiket Dharker, NLM: Stacey, the only thing, the one thing I would like to say to our users, again, thanks, this is great engagement, I think, and we really appreciate all this feedback. Please use, start using the Beta site. You will see as Carrie said, that it is still a work in progress. It is an agile, iterative development, so we believe in pushing updates on a regular basis. We'll keep doing that, but that means you will see issues, but only thing we can promise is we will work if you provide feedback, we will work on it. We are testing these things out. It is going to improve iteratively, but we definitely would want to encourage you to continue using and provide us feedback.

PRS Moderator, Stacey Arnold, NLM: Okay, we've got 60 seconds. I'm going to get one last one in here.

Any chance of adding a New Status button that is something like Closed? As it stands, the Study Complete record may still have future tests associated with it, including results reporting. It would be nice to have a status that is very, very complete. Don't touch again.

PRS Beta Product Owner - Nachiket Dharker, NLM: Yeah, that's a good great question. Thanks for that. Right now no plans for that. I think that depends on. I think that's where...

(Breakout room automatically closed to return attendees to the main session.)