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

CTG Moderator, Wendy Harman, NLM: My clock says that we are at two o'clock. I think we have a very good gathering of almost 100 folks in this breakout room.

We're seeing some questions come in. So if you all are in the, chose the room to talk about the public website at ClinicalTrials.gov, you have come to the right place.

We are going to, as I've mentioned a couple times, but for those of you who are just now joining, please feel free to put any questions you have about the ClinicalTrials.gov modernized website into the chat.

We will welcome all your questions. We will make sure that we're capturing all of them. We're going to answer them as we, as many as we can in line. And we will also take as many as we can verbally and out loud with our product owner, Ms. Christina Robinson.

But first up, we're going to hear a video recording from our Board of Regents Working Group member Dr. Steven Woloshin, who is both a data researcher and has used the site as a patient, actually. And he has, was kind enough to provide us with some feedback about how his experience of using the beta website—the good, the bad, and the ugly, which I believe are, Dr. Fine mentioned just before we went to the break. And after the video, we will hear reactions from our product owner, Christina Robinson,and then we will get to as many of your questions as we possibly can. So without further ado, let's hear from Dr. Steven Woloshin.

Steven Woloshin, Professor of Medicine, The Dartmouth Institute: Hi, my name is Steven Woloshin and I'm a professor of medicine at Dartmouth, and I've been asked to make some comments on the new ClinicalTrials.gov Beta website.

For full disclosure, for full disclosure I'm a member of the National Library of Medicine Board of Regents Working Group on ClinicalTrials.gov Modernization.

So I use ClinicalTrials.gov a lot as a researcher, as a doctor, and I've even used it as a patient. And I like the new website. I think there are a lot of nice changes. I think it's much easier to read, particularly the Results Section. But I think there are still things to improve, particularly about how the messages are targeting the audience. And so I want to talk about a few things today, about searching for studies, about the title and trial descriptions, the disclaimer statement, inclusion and exclusion criteria, and the design and definitions of the trial elements.

So let's start with searching for studies because that's the first thing that users encounter. So the first thing I noticed is when I wanted to do this using the beta website, and the first thing I noticed is that it was a little hard to find. If you look at the very top, you can see it says, We're building a better ClinicalTrials.gov website. Check it out…. And that's how you get to it, by

clicking on it. But it's not obvious. It should probably say, "Click here to use the new website." So this is a small point, but I think it would be important to make it easier to find the beta site for people.

If you use the beta website, this is what the search screen looks like. You enter the condition or disease, or other terms. And I think this is actually, again, it's a small problem, easily fixable problem, but it's not obvious what you would write in here and certainly what counts as "other terms." And this is one place where I think the original site, the classic site, was better. This is what it looked like. And for a condition or disease, it gave an example: breast cancer. For other terms, it gave an example: the NCT number or the drug name or the investigator name. And it's a small thing, but I think that just makes it easier for users. So I hope that they revert back to it.

Once you enter the information, then you get a series of trial titles. And the first thing I wanted to say about this is another small thing, but the NCT Number, the unique identifier number for the trial, which is critically important information because if you're looking at a trial, the public published version of a trial, or if you're looking at some of the FDA documentation, you really need this to make sure that you're reading about the right trial. It's here on the page, but it's really easy to overlook. It's over here in the corner, right? And I think the simple thing should be easier to find. I always find that difficult.

The next thing is the first thing you see is that the status of the trial; in this case, it says Terminated, and then it gives a definition that it's based on futility, not on safety concerns, which is, you know, it's a correct, technically correct definition, but it's not a user-friendly definition. I think a lot of people, consumers or nonspecialist physicians, won't know what you're talking about. They see the word "terminated"—it sounds kind of scary. What this means is that based on an early look at the data, it's very unlikely that this trial is going to be able to establish the benefit of this drug, and so there's no point in continuing, so it was stopped. So make it easier to understand.

Then there's the title itself. I think ClinicalTrials.gov would do well to establish some syntax criteria for how to write these things. This one has a lot of extraneous information, but it's missing some critical information. So it gives you things like the, this is an internal identifier for the company of the trial. That's totally irrelevant to consumers or doctors. And then it gives the acronyms or names of the trial. There may be value of this information, but not for the, for the people who are typically using the site. I think the trial title should be really descriptive.

For example, I made this one up, but I said: This trial is about the safety and efficacy of this drug. Used why? To slow progression of Alzheimer's disease. So this is really clear to people what's being studied and why. And then, for extra credit, you could add the trial design. And here: a randomized trial. Again, the idea is to make the titles more informative.

The next thing that you see on the display page is the disclaimer statement, which is required. And this one says, “The U.S. government does not review or approve the safety and science of all studies listed on this website.”

Again, this is technically correct, but it’s not very informative. And it’s actually a little confusing because it says not all studies, but, so, are some of them reviewed, are some of them approved? The purpose of the disclaimer is to make sure that users, clinicians, patients don’t think that because the trial is listed that the government is vetting the, the quality of the trial, because that’s not what ClinicalTrials.gov. It just lists them.

If you want to learn more, you can read the full disclaimer statement. But that’s difficult, too. It’s this long statement, with all kinds of extraneous information. It has a bit about how the company submits the information, that the CTgov is part of the National Library of Medicine, they don’t fund or oversee all trials listed, and something at the bottom about what it means to join a clinical trial.

Again, all important information, but the disclaimer bit, the most important bit, is buried in the middle, and the most important sentence is really hard to find. But that sentence is: “NLM staff only reviews study information for apparent errors, deficiencies, or inconsistencies.”

They’re not vetting the quality of the trial. And that’s the message that should be up front. So I think we need to provide concise, meaningful disclaimer statements.

Next thing is patients want to know, or doctors want to know, Does this trial apply to me? So, again, here’s the title page with the disclaimer. The question people are going to ask is, Am I eligible, or is my patient eligible? And you can’t get that answer from here; you have to click away to the participant criteria page, and then you get information. Again, it’s good information, but it could be organized in a way that’s much better.

This one says that you have to be 50 to 85 years old and all sexes are available, and then it gives key inclusion criteria. But they’re written in a way that’s really hard for anyone but a specialist to understand. It says you’ve got to meet all the clinical criteria for MCI due to AD or mild AD and have a CDR global score of .5. That’s really gibberish, if you’re not, you know, if you’re not in this area.

If you click on the Show more bit, then you get this really long statement. Again, critically important information for some contexts, but not for someone who’s trying to get up to speed about the trial is about, whether they fit the trial.

I think it would be much better to write something like this. So I wrote this. You know, this is just an idea, but to be clear what the trial is about. So this is: It’s for adults with amyloid plaques seen on a brain scan and thinking or memory problems such as forgetfulness, you know, poor scores on special psychiatric tests, but still able to take care of themselves and do normal activities. So that’s mild cognitive impairment or symptoms that interfere with work,

but they're still able to carry out basic functions independently. That's mild dementia. So now it's crystal clear who this trial applies to and what the point of the trial is.

The next issue I want to talk about is design and definitions. So you want to know something about how the trial is organized.

Ideally, there would be a schematic to show what it means to, what a clinical trial is; how you're eligible; people are randomized to this arm or that arm. But this is done just with text, and it defines the condition, the different arms of the study; it gives the dates of the beginning and the completion of the trial. But what it doesn't do is, the description does not give people a good idea of what is being measured in the trial.

Here, this is what it looks like. It says the primary objective of the study is to evaluate the efficacy of this drug and is looking for changes on a bunch of outcome measures.

And here they are. It lists them, but it doesn't define them. And they are complicated, technical. You know, there's the Clinical Dementia Sum of Boxes, CDR-SB, score; the MMSE; ADAS-Cog 13; ADCS-ADL-MCI.

A nonspecialist won't know what this means. So it should be defined more clearly. If you go to another part of the website—[unintelligible] couple clicks away—you get definitions of each of these things. But again, it's not in a user-friendly format.

This gives all sorts of information about what the measure is, how it's measured, and how it's scored. But it could be much, much easier to use. This section should make it crystal clear what is measured, how it's measured, how it's scored, and what counts. And one way to do this would be to impose some structure. So I'm hoping that CTgov will add structure like this.

Again, this is just a suggestion, but to say the name of the outcome measure and the time frame, and then have headers. What's measured? In this case, three domains of cognition, three domains of function. How is it measured? Caregiver interview, patient examination. How it's scored? In this case, a range from zero, which is best function to 18, which is worse function.

And then what counts? What's the minimum noticeable difference that, that people can, can appreciate? In this case, the minimal noticeable difference on this 19-point scale is a change of 1 to 2 points. And if that information isn't available, and sometimes it isn't available, then to say so, because that tells you something about whether or not you want to be in the trial.

So, bottom line, I like the beta website. I think there's a lot of nice changes. But I think that the messages could be targeting their audience better: one, by making it easier to find the beta website, making the NCT Number more prominent, a better disclaimer statement; and then, throughout the website, more user-friendly language for the title, study description; get the

entry criteria up front, so people know if the trial applies to them; and then make it really easy to find the key terms and outcome measures, again, in simple language.

So that's really all I have to say. Thank you so much for giving me the opportunity to speak today.

CTG Moderator, Wendy Harman, NLM: So lots of interesting observations from Dr. Woloshin there. We appreciate him recording this video, even though he wasn't able to be with us here in person today.

And now we will hear some reactions from our product owner, Christina Robinson.

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: Thanks, Wendy. Yeah, and I want to say thanks as well to Dr. Woloshin, even though he's not with us. Love the thoughtful insights and suggestions, and want to talk in a little bit more detail about some of those now.

So as a reminder, quickly, we're going to go through searching for studies, the title and study description, disclaimer, and the participation criteria.

So one of the things that he pointed out was that we need to make it easier to find. You've got the, that yellow banner across the top of the classic ClinicalTrials.gov. You know, that should be a whole lot easier; actually, starting yesterday we just released a pop-up on the classic ClinicalTrials.gov. It's not going to go out to every person who visits the website, but if you visit regularly, you should see that in the coming days or weeks. And, as I said in, you know, our main session earlier, the beta website will actually be the primary ClinicalTrials.gov starting in June. So when you come to ClinicalTrials.gov, this is what you will see. So here, pretty soon, it actually will not be an issue.

So next up, he talked about searching for studies. You know, he talked about having those, that explanatory content next to the label, so condition or disease, for example: breast cancer. So I do just want to point out there is a little info icon here next to several of these labels. You can click on that. It will open a drawer with some additional information.

But, you know, if the, having that explanatory content on the screen in front of you is helpful, it's an easy fix; I would love to be able to add that back. So why don't you guys tell me now in the chat if you think that that is a worthwhile change. It's an easy fix, and if it's really helpful, then please let me know that now. And we will, we will talk about what and when and how to add that information.

You'll see that, again, in intervention and treatment, and then location, and then study status—so for all of those things you'll, you have, for several of those you have the info icon and you can get additional information.

Then, further, Dr. Woloshin talked about making the study record easier to understand. He talked about the study status being terminated and then the explanatory text that's under that. So "terminated" is the study status. But the text under that, in this case, "To avoid duplication of effort and resources . . .," that's actually provided by the data submitters. And this gets at, you know, a key message that I want to make sure that everyone hears at least once and, hopefully, understands.

You know, as part of the National Library of Medicine, we do not own the study data. We are a library; we make the information available. But the, the data around an actual study belongs to the data submitter or the sponsor of that study. We are not responsible for it. And I'll go into that a little bit in more detail when we talk about the disclaimer. But this is just one example of where that information is provided by the sponsor, and that's typically the organization that's funding or running a study.

So, again, he talked about the clinical trials identifier. This is called an NCT or National Clinical Trial identifier. It's the unique number associated with each of the studies. And, actually, we already knew that that was problematic, that that needs to be bigger, easier to find, front and center; and so we're already working on them.

So I'm going to go into a little bit more detail here. As I mentioned previously, we're part of a library. Just as the libraries provide books, we provide study data, but we don't own it. The sponsors are responsible for the data that appear on the website. But we do make supporting materials and information related to study records available in plain language whenever we possibly can. So that includes explanatory text around different fields, labels, you know, support content; and we have some of that already available on the beta website.

So here's an example of plain language support that we've provided for the patients. This is a page called Learn About Studies. This is general information about clinical research and what it means to participate in clinical research. We have here, additionally, plain language support for data submitters. So this is actually something that was developed and released last year. We're taking a look at it again to see if we can make it even better. And it's a plain language checklist for lay brief summaries. So in that brief description of the study, making that, you know, as accessible as possible to the patient population, the people who really want to participate in those studies.

And then, further, we've added a template to help data submitters write that, whenever possible, if they have, you know, the time and the energy to be able to provide that information.

And then I do want to talk just a little bit about the site disclaimer, because this has been, you know, a work in progress for us for quite some time. We know it's, you know, crucially important for the website. You know, it's, it's been a big hurdle for us in terms of helping users understand, again, that we make the information available and it is a government website, but we are not, you know, responsible for the safety or the science related to those studies.

So we moved it to the top of the page, as I mentioned earlier in the main session—that the users said that they really do want to see it front and center, but that it shouldn't be in the way. So it is a smaller version of the disclaimer now. But you can expand that and see more information, or even click to read the full disclaimer.

Finally, when we talk about the participation criteria, Dr. Woloshin mentioned that it's, you know, you have to go to a different part of the study record to be able to find that information. When you're in the classic website, you have multiple views of a study record. You can see there across the top of the left-hand image, it says Study Details versus the Tabular View and then results, there's a tab for results. When you're looking at the study details on the beta website, you'll see here we have this menu on the right-hand—it'll be on the left-hand side of the record when you're looking at the record—and it floats with you down the page; you can click it anytime into a different section, and it'll immediately take you to that.

What you're looking at on the left-hand side is a condensed view of the study record on the classic ClinicalTrials.gov, and those jump links on the right, where it says Go to, are actually on the far right side of the page. Often folks miss them completely; they don't realize they're there; there's lots and lots of scrolling involved. And so we've tried to make it actually a lot easier for patients, in particular, to find the information that's most interesting to them. So we actually moved Eligibility Criteria and Contacts and Locations to the top of that Study Details tab.

We've also taken Study Design, Arms and Interventions, and Outcome Measures and condensed those into the Study Plan and moved those a little bit farther down the Study Record page. So, again, this is on the Study Details tab, which is really meant to be an easier way for the patient-users to understand a study record.

I'm going to stop there, and we're going to now take your questions and try to provide some, some more interaction for the public meeting.

Wendy, I'm assuming that you've got lots of things queued up for me, so let's get started.

CTG Moderator, Wendy Harman, NLM: I sure do, Christina. So the first question we'd love for you to address is, What is happening with History of Changes? Where are folks going to find it? What's the functionality going to be?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: Yeah, absolutely. So thanks for that question. So the record history is available on the beta website. We have already made a couple of additional releases to the beta history, so there was an initial release and then an update to that. We have more updates coming, more functionality coming. Right now, if you're wanting to compare a couple of versions of the study record, it will take you back to the classic website. The compare is coming on beta, but it'll be a little bit longer before we can actually release that.

CTG Moderator, Wendy Harman, NLM: So I'm hearing there will, there's some functionality available in beta now; continuing to work on additional functionality that will be available soon.

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: Absolutely.

CTG Moderator, Wendy Harman, NLM: All right. The next question is, Some users will need to continue using the classic site until key features are implemented in beta. Can they start using a stable or consistent URL to the classic site now, which will not change again after we make beta primary?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: So that transition that's coming up is a one-time switch. So beta will become ClinicalTrials.gov. ClinicalTrials.gov will move to a different URL. That is a one-time switch. The systems will stay exactly as they are just prior to that. After that transition, of course, we're going to continue releasing features and improving and building out the rest of the beta website. But it's a one-time change for those URLs.

CTG Moderator, Wendy Harman, NLM: Thank you. Perfect. So here's the question that is a big theme over there in the chat, With the ongoing modernization of ClinicalTrials.gov, have there been any changes made to the data or data structure of the API, or is it the same as before?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: Yes, there are changes. We did release a draft version of the new API in January. There is lots of documentation around that. If you go to beta.ClinicalTrials.gov, you will see, I think, it's Data About Studies is our site menu link. There's lots of documentation there. There is a migration guide coming as well. It will not be final for a while because we do want to make sure that it's functioning correctly. We're looking for that feedback from all of you, so please be sure to try it out, provide that feedback, see if it's going to work for you in its current form. And if you have questions, again, submit those through the website using that Feedback button.

CTG Moderator, Wendy Harman, NLM: Fabulous. I just saw one question that was, What information is included in Collaborators and Investigators?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: So that actually includes the sponsor of the study, other folks who are involved in the conduct of the study. And those can be called collaborators and investigators.

CTG Moderator, Wendy Harman, NLM: Okay. I'm looking through.

But in the meantime, I'm curious myself, Christina. What part of this process and, that people can use today are you the most proud of?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: Oh, interesting. Oh, wow. I mean, I really think it centers around the search form. That really is the crux of the whole website, is for folks to be able to find studies of interest as quickly and easily as possible. So I really want that to meet everyone's needs. And as you mentioned earlier, and Catherine as well, it's really difficult because, you know, almost half of our users have never been on the website before. And then we've got those folks who are on it every single day, know exactly how to use it; they want things, you know, fast, now, lots of data all at once. And then you've got folks who are like, I don't know what clinical research is; I don't even know what it means to participate in a study. And so trying to meet the needs of both of those groups at the same time has been a really wonderful challenge. It's been, you know, humbling, frustrating. It's been a great experience. And so I'm really just hoping that, that, that functions as best as we possibly can make it for everyone.

CTG Moderator, Wendy Harman, NLM: Awesome. While I'm going through some additional questions coming in here, there's one that I think is probably more geared toward the PRS side that says, Is there going to be a way to upload lay summaries that align with global registries that require them?

And I'm curious if, you know, I think we do have the study description field there, where we really want to encourage our data submitters to write in lay terms. But would love to hear your thoughts on that.

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM:Sure. Yeah, absolutely. Obviously we're aware that, you know, lay summaries are now being required elsewhere. That is, you know, not a requirement in ClinicalTrials.gov. As, Wendy, you just mentioned, we do encourage data submitters to provide information in plain language. We understand that there's difficulties around that, that it can require additional resources, energy, time. But you know, we, we do want to make sure, again, that ClinicalTrials.gov serves all of our users. And for those patient-users who come to the website, you know, something like nine times out of ten, they are looking to participate in a study. And so they really want to understand what the study is, if it's looking for participants, and what that would involve.

CTG Moderator, Wendy Harman, NLM: Great. I believe there's a few more questions about the API in here, namely, Can you describe where folks can find the draft version?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: Yes. So it is, if you're on the beta website, under Data About Studies, and you can click on Learn About the API. There is some introductory language there, but that, that page is actually the API itself. So, and there's, there's lots of documentation around that, including the details of the actual study, the data structure.

CTG Moderator, Wendy Harman, NLM: Fabulous. And it looks like one of our intrepid participants here has included the link. Thank you very much.

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: Thank you so much.

CTG Moderator, Wendy Harman, NLM: That's terrific. I'm getting a lot of questions about exact timing, which I know that we can't, we don't want to pinpoint the exact moment, but looking for some ballpark timing around when the API will be final, when History of Changes, when the record history will move over. Curious if you can just explain what's happening behind the scenes a little bit.

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: Yeah. So there is lots and lots of work going on. Obviously, we, I talked earlier about the fact that we are updating the search functionality. It's really not the way that, you know, the search functions or the search results, but the search form itself. So we're updating that right now and getting ready for that transition to make the beta website primary. We do know that, you know, record history still needs some additional work; we need to provide download and XML. So, you know, and the API is actually a much bigger chunk of work than even any of those things, and so it's going to be a while before we can actually call that API final.

But, I just want to keep reiterating that the classic website, the classic API, all of those things are going to continue to be available in parallel for quite some time. So no panicking. There will be lots of communications. We'll make sure everyone knows in advance of those, those systems actually retiring.

CTG Moderator, Wendy Harman, NLM: Great. And we have a question here that says, We knowing that over half of the visitors to ClinicalTrials.gov are first time users and that those folks are probably people who are sick or they're friends or relatives of folks who are sick and trying to find a study to participate in, how are we measuring the effectiveness of modernization? How well we are handling that, that patient, those goals of that kind of user?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: So in addition to the Feedback button, which we've mentioned several times, there is also a survey available on the beta website. We will look at the survey data regularly and use those metrics to be able to evaluate if we are, in fact, meeting our goals.

CTG Moderator, Wendy Harman, NLM: Yeah, I would, if I may, just also say we've really tried to design the, the system so that—or all of the surrounding navigation and content that you find that is not the actual study details that a data submitter owns and has entered—we've tried to make that as patient-friendly as, as possible and try to really provide a lot of context throughout the experience of searching for a trial. So that is one of the main goals that, that we have and that we will be measuring over time and are baselining now.

There are some questions here about the RSS feed. Will it stop once the beta version becomes primary?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: That's a great question. I will have to look into that to get confirmation. I don't want to answer because I don't know with a great degree of certainty, but we are looking at replacements for the RSS feed because we know that that functionality is really important. For anyone who's not using them currently, that's a way to get updates on a query, like a search for a certain kind of study, or updates to individual studies. And so we are looking at ways for you to get those updates coming directly to you, as opposed to having to go and conduct your search over and over again. So yes, we know that, that that's really important functionality, and we will be making something available.

CTG Moderator, Wendy Harman, NLM: Great. Thank you so much. There was one question that I believe we might have answered in line, but folks are curious. Oh, wait, I think we already did it. Sorry.

When you enter a keyword into the search box like, as a free text, is it is it purely free text or will there be any, can you select from various vocabulary terms like MeSH? I'm not sure if everyone on the call here understands MeSH, but maybe you can help us out.

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: Yeah, sure. So, we are not using any vocabularies at this time. Sorry, just one second here. The keyword fields, when you do search those will, you will get, excuse me, auto-complete options that you can then choose from, or you can continue searching, entering your term as you've been entering it. But no, we are not using any of those vocabularies at this time.

CTG Moderator, Wendy Harman, NLM: Okay. Thank you. I'm looking through the chat. Our moderators are doing a great job of answering.

Here's another date question for you, Christina. I know we love these. When will, when will the current version of ClinicalTrials.gov be retired?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: So sometime in 2024. We don't have an exact date. There is some work that actually has to happen in advance of that. So there is plenty of time for everyone to become accustomed to the new system, for us to continue building it out. So 2024 is when the classic website and API will be retired.

CTG Moderator, Wendy Harman, NLM: Thank you. And I believe Rafis just hopped in the chat and was helping us out with something that I think is probably important to call out to the entire group.

We have a question that is been asked by several folks about—Do you already know what the URLs are going to be on the classic site after June?—so that they can start using them before that, that cut over. And Rafis was able to answer that the classic API will continue to work on the current URLs, and everything else will work on classic.ClinicalTrials.gov.

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: Thank you, Rafis. Great to have you with us.

CTG Moderator, Wendy Harman, NLM: And Christina, we have folks asking if you would speak to uploading lay results summaries.

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: Oh, goodness. So, yes, I know that that's another hot topic in the patient advocate world. So we do know that those are, you know, really desired. We would love for those to be made available. There is no requirement currently to provide those as part of ClinicalTrials.gov registration.

CTG Moderator, Wendy Harman, NLM: Okay. In—I don't know if you know the answer to this one, Christina—but in the current beta site downloads someone wants to know, Can we get all fields of data, including History of Changes, in that download? Is that going to be possible?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: So we are looking at making that possible. So currently, yes, you can get all publicly available fields. We are not currently offering the, the history, the multiple versions of a record. So if it's been updated many times, you can download, I think, just the current version. We are looking into the possibility of that. There are some technical complexity with making that available. But we do know that there is a desire for that, and so we have to sort of weigh the level of effort of that work against, you know, all of the rest of the work that we still have to complete, and then prioritize accordingly. And, again, that prioritization happens based on the feedback that we get from the users.

CTG Moderator, Wendy Harman, NLM: That's right. So, I will take a couple of, we'll do a couple more here. Is there anything planned that would allow a patient or a provider to be made aware of new trials for their particular disease or geographic area, for example?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: So I think what you're referring to there, that, I think that gets at, again, that RSS replacement. So we do want to be able to send users updates to their searches, and we are looking into that. That's something that will come later this year, but we don't have it currently.

CTG Moderator, Wendy Harman, NLM: Fabulous. And what about saving a search? Are people going to be able to do that?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: So that's essentially the same thing. So saving the search, getting search updates, getting updates to a particular study record—all of those things are coming.

CTG Moderator, Wendy Harman, NLM: Great.

I'm curious if you could talk a little bit about the link between ClinicalTrials.gov and, say, a published article in PubMed or at PubMed Central. How are we connecting some of these trials to articles about them?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: So currently we auto-index to study or, excuse me, to publications in PubMed for any publications that have included the NCT Number. So we are ingesting from PubMed that way. We are looking at the possibility of doing, providing additional information, but there's, again, some complexity around that, and it'll take some time before we're able to do something like that.

Any other questions?

CTG Moderator, Wendy Harman, NLM: Are there going to be any languages supported, outside of English?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: So currently ClinicalTrials.gov is only offered in English.

CTG Moderator, Wendy Harman, NLM: Excellent. What about BESH studies?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: Okay. So, for anyone who is not aware, BESH studies are basic experimental studies involving humans. There is a link that I can drop in the chat for more information around BESH studies. So those that meet the NIH definition of a clinical trial will be included on ClinicalTrials.gov.

CTG Moderator, Wendy Harman, NLM: Perfect. This is an interesting question about glossary terms; someone suggesting that we make those terms even more friendly for lay users. I'm curious if you can just discuss a little bit about how we formulate those, those glossary terms and figure out what all needs to be included there.

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: Yeah. So we do hope to make improvements to some of the glossary terms. Some of them are legally defined terms, so we may not be able to change them, but there are some that could be improved, and we are looking into the possibility of doing that.

CTG Moderator, Wendy Harman, NLM: Thanks. Fabulous.

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: So I think we just have a few more minutes before we'll go back to the main session. I just want to point out one more time that if you go to beta.ClinicalTrials.gov, the Feedback button there is in the bottom right-hand corner. If you want to participate in user research, you can leave your contact information, and we might reach out to you to involve you in some of those efforts in the future. But all of that feedback is reviewed; we look at it on a regular basis; it's analyzed, prioritized; we incorporate that into our work processes. So please, by all means, keep the feedback coming.

Wendy, we maybe have time for like one, maybe two more questions, if there's anything else that sort of rises to the top.

CTG Moderator, Wendy Harman, NLM: Okay. I want to search for a really good one.

Oh, thanks, Ryan.

Looking, I'm looking for the best one.

You're still. Some.

Oh, Duncan, we will. That's a good suggestion. He's, they are asking if we can include some of the questions and answers when we send out the, the slides.

We will certainly consider that. I think that's a good idea. And, as well as some of the links that have been shared.

So I'm curious, Christina, if you can just share a little bit. You've talked about the, the API and record history, but what other features are you excited to continue to enhance over time after beta becomes primary?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: So, we know that we need to make download available in XML. So that's a big one. We have some technical work to do in the background. That's not really worth going into here.

We do want to provide some more support information for the patient-users to help them understand, and help them understand and use the website a little bit better, find studies that are actively looking for participants. So, yeah, that's, that's, that's, those are probably the things that I'm most looking forward to.

And onboarding, actually—that's something that I didn't touch on previously. So when one of those new users comes to the website, give them some kind of guidance to say like, Hey, here's a really, really quick, simple—like, Here's how you use the website; here's what you can do here. So allowing, allowing for those, those new users to get up to speed quickly.

CTG Moderator, Wendy Harman, NLM: Great. And.

Okay, it looks like we're going to get sucked back in. And please do remember to continue to provide feedback.

One more question as we close up here, Christina. Curious if you can talk about some of the plain language materials that we'll have available to help folks navigate through ClinicalTrials.gov.

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: Sure, absolutely. So we do already have a couple of pages on the website. One is Learn, let's see—About ClinicalTrials.gov, where you can learn about the website itself.

There is another called Learn About Studies. We're working on a how-to page for the search feature.

We are also working on one that will help users understand the study record, so when they go into a study and they're reading all of that data from the data submitter, you know—figuring out exactly what that means.

So, and lots more. I just can't think of all of it off the top of my head.

CTG Moderator, Wendy Harman, NLM: Well, thank you very much for, for answering so many of these questions today. There is one more about JSON:

Do we have any plans to include the download in JSON format?

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: We already have JSON available; that's been available since the very beginning.

Yes, it is definitely the more common format, but because ClinicalTrials.gov has been around for so long and so many folks are using XML, there is quite a lot of demand for it. So we will make the XML download available.

CTG Moderator, Wendy Harman, NLM: Fabulous. Well, thank you so much. And thanks to everyone who participated here. As we're seeing some, some notifications here:

Please leave the breakout room, but do not leave the meeting because we were, we're all going to get back together again.

So hopefully you can pick the right button there: Leave breakout room. And we will see you back in the big group.

Thank you so much.

Christina Robinson, ClinicalTrials.gov Beta Product Owner, NLM: Thank you, everyone.