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

Moderator, Anna Fine, ClinicalTrials.gov Acting Director: Thank you, everyone, for joining the meeting on ClinicalTrials.gov Modernization. We'll begin at 12:30 Eastern Standard Time, so please stand by as we welcome and more are joining.

Right. The time is now 12:30 PM. Dear participants, thank you for joining today's meeting. Good afternoon to my East Coast colleagues. Good morning to the West Coast and good evening across the pond. I'm Anna Fine. I'm the program lead at ClinicalTrials.gov and I'll serve as one of your moderators for today's meeting. I can't wait to introduce you to our first speaker. But first, let's go over some housekeeping items. The meeting is being recorded and the recording will be made available with the slides within a few weeks. All participants will be muted during the main session and throughout the meeting, but will have the opportunity to interact via polls, chat directly with the moderators and will have open chat during our breakout sessions.

Now, I believe most people have experienced using Zoom, but if you're having any difficulty with your audio or video, you can use the Chat Box feature in your toolbox and selecting Tech Support or meeting Moderator for help. To see your toolbar, it helps if you exit the full screen. And so if you're not in Fullscreen mode, you'll be able to see at the bottom your toolbar, where you can see how to enable your chat and just have discussion with any tech support or moderators that you need. Also from the toolbar you can select captions if you wish to have closed captioning for today which is enabled.

And later in the program we'll also have an option to join breakout rooms. So speaking of breakout rooms, let's review the agenda for today. We have a great lineup of speakers providing introductions and orientation to the modernization effort. We'll be focused on users and how perspectives were incorporated into the designs, followed by introduction to both the beta products and the status of their progress. Then we'll dive deeper into the discussion around the products in a breakout room, where you'll be able to join one of the two rooms. And it will be open chat where you can type any of your questions and interact with others in the meeting.

Now I have the pleasure to introduce our first speaker, the Director of the National Library of Medicine at the NIH, Dr. Patricia Brennan. She's been with us since 2016; as a nurse and an industrial engineer. She has brought to NLM a broader definition of health to include social experience of patients, and as an engineer or focus on data science guiding NIH to data driven research and discovery. We greatly appreciate her support and the vision of ClinicalTrials.gov positioning us into the future. Welcome, Dr. Brennan.

Patricia Brennan, Director, NLM: Good morning, Anna, and thank you very much for the introduction. I want to thank the almost 400 people who have joined in for this conversation this afternoon. Excuse me. As part of the Federal Government, we believe that making sure that our resources are available, accessible, desirable and as easy to use as possible to all the

publics that we serve. Having meetings like this, conversations and dialogue with those of you present, is one of the ways we make sure that we are meeting our mandate.

Now, many of you are familiar with the National Library of Medicine, but some of you may not be. So I'm going to take a few minutes and tell you about the National Library of Medicine. On the screen in front of you, you see our beautiful historic building, the low building in the front, and our tall research building in the back. Now, not only are we not in those buildings because of the previous couple of years of pandemics, but we're also in the process of renovating these buildings. I can tell you more about that later. But today, what I want you to know is that we're almost 200 years old. The National Library of Medicine has, draws its roots from serving as an Army field hospital library before the Civil War. We grew over 50 years, and with the leadership of John Shaw Billings became a repository of biomedical knowledge to now being the largest biomedical library in the world. Now, as a biomedical library, we have both print and electronic collections for every possible domain of medicine, biomedicine and health sciences. We host a History of Medicine Division, please return. We host a History of Medicine Division, and we are in very proud of the fact that we also have the most up-to-date genomic databanks in the world. In addition, we have an 8,000 member strong Network of the National Library of Medicine that touches almost every county in the United States with the human engagement that helps us support our mission to enable biomedical research to be able to support health care and public health and to promote healthy behaviors among all.

Let me go back. Let's go to the next slide now.

I began by telling you some of our history. We are very proud of our first two almost 200 years of service. The collection of biomedical information requires that we collect broadly, and that means not only do we collect books and journals, but we also, as you'll be hearing about today, collect information about clinical trials. Our commitment is to make this information available, and while for over a century our beautiful buildings, which were, have only been here in Bethesda for about 50 years. Our buildings served as the primary point of interaction with our public. We used to be in downtown Washington, and before that, as I said, we were in a field hospital. But around 1960, we moved into the NIH campus and became part of the NIH. And this was also, as you remember, the origins of computation and information technologies applied to many disciplines and many fields, including health and health care.

ClinicalTrials.gov is one of our key electronic resources. It was made available early on, to ensure both that public reporting of clinical data and public accessibility of the possibility of enrolling in trials was made available. But it built on two key parts of the National Library of Medicine, the Lister Hill National Center for Biomedical Communications, which employed everything from satellite technology to new kinds of laser discs in the '90s to get health information out, and the National Center for Biomedical Biotechnology Information. The NCBI was chartered by congressional legislation in the late 1980s and has become a world class powerhouse making information available.

The ClinicalTrials.gov operations sits within the National Center for Biotechnology Information and we're proud of the support. But, importantly, what you should understand about that is, it also allows us to leverage all of the digital technologies we have available at the National Library of Medicine in support of ClinicalTrials.gov. So we are able to use effective search mechanisms; we are able to connect citations, and register studies in our ClinicalTrials.gov repository with related information and PubMed and PubMed Central, so we're able to get additional information out to individuals. This forms the basis of what we are involved in right now. The building of the 21st century, the Library.

We are leading innovative research here at the National Library of Medicine to envision a future of data-driven health and data-powered science. This means we study algorithms and build new kinds of visualizations so that we're able to better understand things, like how does Covid appear in wastewater, or what is the proper way to describe the inheritance property of a virus? We have many scientists that are looking at how we can best use electronic health information, properly protected, to both preserve the privacy of individuals, as well as to better understand and learn from clinical practice. All of this idea of continuous innovation has driven our work for the clinical trials. Gov modernization.

Next slide, please.

The ClinicalTrials.gov modernization has been an NIH-wide initiative envisioned first by our NCBI colleagues to make sure that ClinicalTrials.gov continues to be a trusted and valued premier public health resource that provides maximum value to the public, and serves its mission well into the future.
As you've seen in previous materials about ClinicalTrials.gov, you know that we have two primary responsibilities: recording information about studies, which may mean the early declaration and submission of a study structure, its key questions and the kind of outcomes that are expected and then reporting the results of those studies. Over the past few years, ClinicalTrials.gov has taken on new responsibilities to demonstrate to the public the value of federal research, because we provide to the public research findings as quickly as possible, sometimes faster than they appear in research publications. And certainly in a way that aligns with the original declaration of the study. What questions are we trying to answer, and how would we know that those questions are answered?

Yet we know that a venerable computer resource designed initially in the late 1990s, might not serve the 2025 community that, in the way it needs to serve. Thus we undertook this modernization process several years ago with significant financial support from the NIH, we have gone forward to create a social, technological and information environment for the future of clinical trials.

Next slide, please.

This is one of a series of public meetings that we're holding to make sure that we hear from the public and learn from the public and report to the public what we are doing with public funding to improve this incredible resource.

Today you'll be learning about an overview of the modernization effort. We're going to be sharing new information and actually let you walk through the new ClinicalTrials.gov website, which is where most laypeople and clinicians encounter the system, and the Protocol Registration and Results System, which is where our researchers go to enter their data or enter their results. Most importantly, we want to use this time as a question for our users and our stakeholders to ask questions and also to provide us with feedback and ideas about what the future might begin, might require.

I'm going to ask you to begin right now with thinking about, what do you want the NLM to learn from this meeting today? What has been your experience, or that of your patients, or that of your family members as they've tried to use ClinicalTrials.gov. For the investigators in the room, how well do our structures, our interfaces, and our tools support what you are trying to accomplish as you report the results of your research or try to make a registration for the study?

We have learned that ClinicalTrials.gov is not always quite as easy to use as we'd like it to be, and that's why this public engagement and our massive investment in creating a good front end to ClinicalTrials.gov is really necessary. But while we've been working on creating an interface that makes sense, is easy to use, is pleasing to use and is understandable, our technologists and our engineers have been working in the background to make sure the data model underlying ClinicalTrials.gov and all the interoperable interactions that are needed to make a modern computing system work properly in a safe and secure fashion happen every day. This requires attention to safety and security, to the integrity of our software development process, and most importantly, to the integrity of the data that is deposited with us. We have, and the ClinicalTrials.gov operation here at the NLM, we have a large number of individuals we call "curators," who help us make sure that information that is entered by our scientists and used by our public is accurate and consistent with the way the science was conducted. This human engagement really makes sure that we are monitoring our studies properly and describing them in the best way that makes it useful to the public.

Let me go to the next slide, please.

Every institute at the NIH has a Board of Regents, a National Council, or some other public advisory board. These public advisory boards, known as FACAs, or federal advisory groups that were chartered under the Federal Advisory Committee Act, serve as advisories to the Secretary of Health and Human Services, the Assistant Secretary of Health, the Director of the NIH, and to me personally.

We have 18 members of our National Board Library of Medicine, Board of Regents; half of these are appointed by the Secretary after being nominated. They represent experts from

across the country, from consumers and citizen scientists to genomics experts to clinical practice experts to public health experts. We also have among our Board of Regents, members of the uniformed services, including the departments of the Army, the Navy, and the Air Force. We have a representative from the National Science Foundation. We have a representative from the Uniformed Services Health Sciences University and from the Library of Congress and our sister library, the Agricultural library.

This group meets three times a year to deliberate important actions, and most importantly, form solid Working Groups, such as the one that's guiding this meeting today to make sure that we reach the public and we have a systematic way of understanding and listening to the public.
What happens as these Working Groups conduct their activities, is they prepare reports that are then referred back to the Board of Regents for deliberation, and entered into the public record of our National Library of Medicine Board of Regents. This kind of systematic public oversight makes sure that we are being good stewards of the federal dollar and also makes very sure that we are being good citizens of science, to make sure that what is needed to be known by our past, present and future research can be learned.
Now, ClinicalTrials.gov largely focuses on clinical trials, that is, studies comparing the effectiveness or outcomes of certain interventions to address specific clinical problems. While we address problems that are unique to the United States, our Board of Regents is quite well aware that the ClinicalTrials,gov outreach covers the world. It's important for us to understand the global reach of our ClinicalTrials.gov networks, because this allows us to keep abreast with scientific discoveries around the world and also to contribute to them in a systematic way.

So the work of the Board of Regents is to make sure that the National Library of Medicine, as a part of the NIH, fulfills its mission by serving science and society.

Next slide, please.

Today I'm here to thank you, and to summarize the charge to the Working Group. The National Library of Medicine, Board of Regents Public Service, Working Group on Clinical Trials Modernization, which is a mouthful of a name, has a very specific charge. It's intended to explore topics related to the ClinicalTrials.gov modernization, such as, but not limited to the various ways the National Library of Medicine can maintain the integrity of the clinical trials as a trusted government resource, maximize the utility of the growing corpus of information we have, and connect with stakeholders to engagement to ensure that evolving needs are understood and are considered.

We work very closely with our sister federal agencies, including the FDA, to make sure that the information that is necessary to demonstrate the effectiveness of new interventions being brought to the public are available and accessible and understandable to all. Our responsibilities at this point in time focus on, but are not limited to, clinical trials conducted in the United States, with a global reach of recording trials that are conducted around the world.

This work of the Working Group has been particularly critical to me in my leadership here at the National Library of Medicine for the past several years by having a outside community communication to interact with and to drive our modernization process. We are able to demonstrate to the NIH how carefully we are trying to support the community of science that covers the entire NIH. And, frankly, the world. Our research efforts in learning how to better understand the reporting of clinical trials has helped us to improve the interface and make sure our data structures are up to date and modernized.

We have a special effort in something called the User Experience evaluation that our Working Group has been quite interested in, to make sure that we actually provide test cases for the wide range of users to be able to make use of our system.

The work of the clinical trials Working Group could not happen without the support of the Board of Regents, and in particular, I want to acknowledge two people that are with you today. Lourdes Baezconde-Garbanati is a member of the Board of Regents and she is the chair of the Working Group, and Jennie Lucca from the National Institutes of Health Children's Inn is part is one of our public members.

I'd like to take a time now to turn and introduce you to Dr. Lourdes Baezconde-Garbanati. I've been delighted to get to meet her and work with her on her four years here at the National Library of Medicine Board of Regents. She's been a member of the Working Group for several years and became the second chair of this Working Group. Dr. Baezconde-Garbanati is now a tenured professor at the Preventive Medicine Department of Preventive Medicine at the Keck School of Medicine at University of Southern California. She's the founding director of the Center for Health Equity in the Americas and co-directs the Global Health Leadership track in their MPH program. Dr. Baezconde-Garbanati has a long history and a wide history of national service in international scholarly engagement, particularly in the areas of culture and community health, with an emphasis on Hispanic and Latino health. Dr. Baezconde-Gabanati's experience in reaching to the public has helped to shape the clinical trials Working Group and brought us to a point of engagement that will be explored in more depth this afternoon. Thank you very much for joining us here today and thank you very much, Lourdes, for being our partner in this process.

Anna, I'll turn back to you.

Moderator, Anna Fine, ClinicalTrials.gov Acting Director: Right. Thank you, Dr. Brennan. And as Dr. Brennan had provided a lovely introduction. Take it away. Dr. Baezconde-Garbanati.

Lourdes Baezconde-Garbanati, Working Group Chair: Thank you. Thank you, Dr. Fine and Dr. Brennan for that introduction. Welcome, everybody. As you know, I am the Working Group chair, and I've been honored to serve on this Working Group along with my colleagues.

Next slide, please.

And so I'd like to introduce you today to some of the folks behind the scenes that have been helping to prepare for this modernization. Lyric Jorgenson is one of our members. Lola Ogunyemi, Carrie Dykes, Seth Morgan, Pamela Reid Kearney, Jennifer Lucca, Nancy Smider, Sally Gore, Alissa Gentile, Anna Fine, Joseph Ross, Stephen Rosenfeld, Barbara Kress, and Steven Woloshin. And I'd like to mention in particular that today you'll be hearing from some of our Working Group members, in particular from Ms. Luca, who represents the patient/patient advocate perspective; from Dr. Dykes, who represents the data submitter perspective; and Dr. Woloshin would be representing the data researcher perspective.

Next.

Today we have an icebreaker, and we'd like to know what perspective you represent today. And so, as you can see, we have something on your screen that is a little poll, and if you could please respond with a question, What perspective do you represent today?

And please scroll all the way down just to make sure that all of the different perspectives are represented. And, you know, we have here patients; data researchers; people from academia, industry, government; information specialists; librarians and regulators and those involved in regulatory affairs.

So, I think we're almost there.

This is great. There's it seems to be quite vast representation.

And so the results are that the majority of you, about 24%, are academia data submitters; followed by industry and also data submitters; and then by information specialists and librarians, as well as data researchers. And then we have our government and data submitters, and our patients and their advocates. Thank you, everybody, for being here today.

Our next, next slide, please.

So I wanted to tell you a little bit about the Working Group efforts to date. As you could see, we've done quite a lot of work. We've held 15 Working Group meetings since 2019. We've met a minimum of three times a year and have the opportunity to really provide input into some of the design features, support these public meetings, and also provide feedback on the communication efforts. We've shared ideas and heard the various needs from all of the different perspectives that you represent today and have had the opportunity to make suggestions and decisions as to where the needs may have been conflicting or what we needed to focus on most.

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So as you can see, and you may have already received this, we've issued two progress reports, and these progress reports had the pleasure of being reviewed by the Board of Regents and

summarizing the progress and the phases of the ClinicalTrials.gov modernization. And we're working on the release now of a third report for this fall that would summarize the efforts from this year, including the input that you're going to be providing at this meeting. So please don't hold back. Let us know what you're thinking.

The reports include alignment of ClinicalTrials.gov and the PRS Beta with modernization, priorities and goals. Our public communications related to modernization and beta releases, research and support of modernization efforts, and the future modernization activities. So we're really excited about these reports and are looking forward to that third report that will be released, also with your input.

Next.

And, you know, it really takes so many of us to do this work. So in addition to the folks I introduced at the beginning, I want to also give you this list of all of the people that have been really a part of this journey with us. And as you could see through the years, it wouldn't be possible without the NLM team. And I want to thank them in particular. And you're going to hear from some of them today. But there's just so many people that have been working behind the scenes. And I've had the pleasure of interacting with many of them over these few years as a Working Group member. So I want to thank you all for being here. Thank you to the modernization team that has worked relentlessly on this issue. And I'll turn it back now to Dr. Fine.

Moderator, Anna Fine, ClinicalTrials.gov Acting Director: Thank you to both Doctors Brennan and Baezconde-Garbanati, for kicking off the meeting and for your support and leadership. And also our gratitude to our Board of Regents Working Group members, both who are speaking today and those who are joining to observe the meeting.

I'll now provide a quick overview about the modernization effort.

The modernization effort is aimed to improve the user experience, by upgrading the technical infrastructure, and to support the existing regulatory and policy framework. We were due to upgrade the system, accommodating the growing body of research. While we have almost 460,000 studies registered with ClinicalTrials.gov currently available for you to search, but we needed to make sure that our technology was keeping up with that research body as well.

Now, as you saw from the poll, there is a variety of stakeholders with us here today, and we think every stakeholder is important. We didn't want to focus this effort just on one user type group. We serve a variety that are both internal and external, and you're at the forefront of all the improvements that we're making. The needs of the stakeholders do vary greatly, which makes our work even more fun. Our teams have engaged with all of them throughout this effort, including librarians, journal editors, and third party data providers, just to name a few who aren't even listed on this slide.

Now, from the outset, this project was intended to be a multi-year effort. With the first year focused on stakeholders, we wanted to hear what you'd like to see in a modernized system. Through meetings or request for information (and RFI), the Board of Regents, we compiled the feedback and organized ourselves into teams and developed a roadmap. We built a minimally viable product and we made it available for further refinement, feedback, and growth. We're now in our fourth year and have so much more to do, but we can see the journey to the finish line.

Both ClinicalTrials.gov has a beta website and the submission portal, the Protocol, Registration and Results Reporting, known as the PRS, has a beta version available. We made these products available publicly in parallel to the existing sites, where a user can get familiar with them and we can learn from real world use. This also means that our amazing teams are maintaining four sites in the interim until the new sites are stand-alone. So we look forward to sharing more about the states of these products at today's meeting.
From our launch and throughout 2022 and this this year to present month, we've had an increasing number of releases adding features to the sites based on the feedback that we received and reprioritizing some of the features. You can read and stay up to date about these releases on the notes pages which are publicly accessible, including the PRS Release Notes page. Our next speakers will share more about those perspectives that provided input into the beta website and how such feedback is incorporated into the design.

So I'm delighted to turn the meeting over to our next speakers, who will underscore the user's needs, which is at the heart of why we're making ClinicalTrials.gov better for you.

So our first speaker that I'd like to introduce is the CEO of The Children's Inn at NIH, Jennie Lucca. She is a seasoned human service professional with over 20 years of experience in the non-profit sector. Jennie holds a master's degree in social work, with a focus on policy planning and administration, from the Catholic University of America, also a bachelor's degree in child psychology from the University of Minnesota and a Non-profit Management Executive Certificate from Georgetown University. Under Jennie's leadership, The Inn was awarded the Montgomery County Chamber of Commerce's 2022 Visionary Award. Jennie was also honored by Federal Health IT in 2022, where she was presented with the Leading for Impact Women in Leadership Award. Jennie, thank you for being with us today and telling us more about The Children's Inn and the patients that you serve that we've got to know really well.

Jennie Lucca, CEO, The Children's Inn at NIH: Thank you, Anna, and welcome to all of our participants today. It has been really an honor to be part of the modernization effort, both through my membership on the NLM Board of Regents and also through my role as CEO at The Children's Inn.

At the Inn, every day I meet families who are navigating the most difficult journey of their lives, and that's having a child with a rare disease for which there are very few treatment options or a more common disease that has been resistant to standard treatment options. So they really benefit from having easily accessible, accurate information at their fingertips to help them

navigate this journey. And as Anna said, my role today is to provide the layperson, a patient and family perspective, which is an important one. It's a stakeholder group that was able to provide some feedback on the modernization effort and also will, will benefit from this effort for many years to come.

Next slide.

So The Children's Inn is a non-profit organization. We're located right on the campus of the NIH. You can see in my zoom background the playground of The Inn right behind me and then the Clinical Center just off in the distance. And we provide lodging and support services for very sick children and their families, teens, and young adults up through age 30, while they participate in clinical research studies at the NIH.
For most of the children who are staying with us, a clinical trial at the NIH Clinical Center represents their best hope for a treatment, a cure, sometimes just the name to their diagnosis. And everything we do at The Inn strives to reduce the burden of illness on families, make childhood possible, and help advance the NIH clinical research mission. Information relates very directly to reducing the burden of illness on families.

The Children's Inn, next slide, The Children's Inn operates as a private non-profit with the NIH. We raised the money to build the building and then gifted it to the NIH, which is a federal entity, and then we operate as a non-profit raising almost $10 Million a year to operate The Children's Inn. This is a snapshot of our impacts about — it's now closer to 16,000 families, and those families make thousands and thousands of visits over time, have participated in 500 or so clinical trials, and this represents major significant advancements in the treatment of cancer and bone and growth disorders, mental illness, genetic conditions. And you can see it's a very global population. We have families from all 50 states and we're up to 106 countries.

I mentioned, next slide, I mentioned part of our mission is to make childhood possible, and specifically what I mean by that is to give children the opportunity to meet friends, build new skills, try something new. For most of the kids who are staying with us, it's just not possible for them to safely participate in many of the normal activities that kids participate at home. And here, I just thought I'd show you a few photos, recent photos of, of children and young people at The Children's Inn participating in some fun, and also educational events, from National Pizza Day to a science experiment; on the far right is a reading club with our in-house therapy dog, Zilly. Local sports teams do a lot to support The Children's Inn, and here you see young people participating in a in a soccer training. And then of course, we try very hard, and especially over the last couple of years during the pandemic, to get families outside the gates of the NIH, and so at the bottom corner is sailing on, on the Chesapeake, which is something that they always look forward to and something new, really for some of our international families.

I do want to show you just a sneak peek, because I think about the modernization effort and just the future of medicine. This is a rendering of our Children's Inn of the future, which is set, we are set to begin construction in 2025. So it's a renovation of our existing building and then

about a 20,000 square foot expansion. And that expansion really directly is our vision, which is in partnership with meeting the changing needs of the NIH. And as science evolves and medical treatments become more expansive, we want to evolve too. So our new Children's Inn will be able to accommodate every child, regardless of the criticality of their illness. And we're looking forward to having more families as well.
Turning specifically to the modernization efforts and The Children's Inn collaboration with the National Library of Medicine, it really started in 2016 when Dr. Brennan was, visited The Inn as part of her orientation as the new Director of NLM. And it was, it was during that visit that I shared with her this difficulty families were sharing about understanding the medical information that they were receiving during the day from their medical teams. It was overwhelming. It was complicated. And they'd come back to The Children's Inn in the evening and turn to Google — which we all know Google doesn't, is not the most reliable source, and especially for our families who had have such rare illnesses. And she very quickly put an amazing team together to help us, from from NLM. It started with an assessment and an evaluation to really understand what families needed. And around the same time, The Inn launched our own strategic plan aimed at reducing more burden of illness on families, and just trying to do more to help our clinical partners and the families that we were serving.

So through, ultimately a collaboration with NLM, with the All of Us research program and also patient recruitment, we began to offer what we call Caregiver Cafés, and that was in response to, a direct response to families' requests. And the Caregiver Cafés are biweekly programs. They are focused on increasing caregiver knowledge and access to resources at the National Library of Medicine. They provide caregivers with information to better understand their child's medical condition, and they also provide a safe space for caregivers to network and support each other. For many of the families who are staying with us, they've never had the opportunity to meet another family or another patient that shares their same illness.
So to date, we've held several of these caregiver sessions and some of them, for example, have focused on finding clear, clearer definitions of their child's disease, how the disease progresses, the treatments that are available to them, and the lifestyle changes that might impact a child's health. Families requested more information on genetics and how to increase their skills online and how to use different search engines to get the information that they need. Most recently, a session focused on interpreting medical research materials. These sessions are offered in English and Spanish, and we have the opportunity to translate them into other languages as well.

And so then this led to The Children's Inn families being invited to provide feedback on the beta site and share more about the difficulties that they were having in in trying to find accurate information. There was also a need, which we all know, to understand the outcomes of past clinical trials — that was important to families as they were looking at participating in new clinical trials.

So this is going very well. We were excited to be able to participate and as I understand it, families will continue to provide feedback through 2023.

Here is an example of one of those families. This is Billy P. And his mom, Gabriela, who come from Ecuador. Billy is 16 years old and was diagnosed, is diagnosed with Job's syndrome. He is participating in a study by being done at NIAID. And Job's syndrome is a rare genetic disorder. It affects, really, almost all the systems of his body. He deals with recurrent skin infections and lung infections, bone fractures, scoliosis and vascular changes as well. The incidence of Job's syndrome is just one in a million, and there was no treatment at all at home for Billy in El Salvador. He over, he visits The Inn about every six months, and he's preparing now for a bone marrow transplant from his sister. His mother participated in the Caregiver Cafe sessions and her questions for the leaders of those sessions were, How can they help Billy understand his disease, the many treatments, the many procedures, the many surgeries that he will need to endure in an aged-specific way? And that has been her big question and also the reason why she attends those sessions. She also had the opportunity to provide feedback on to the modernization effort and was taught how to use ClinicalTrials.gov, which has been just critically important to her and her family back home.

Finally, I have one more patient perspective, and this is Autumn. It's a video. Autumn is a young child that's participating in a clinical research study at the NCI, the National Cancer Institute for neurofibromatosis type She's benefited a lot from this clinical research study, and in this video you'll hear from Autumn and her mother in their own words.

(Video) Autumn: My name is Autumn. I'm nine years old and I come from Kansas.

(Video) Lindsay, Autumn's Mom: We come to The Children's Inn to go to the clinical trials at the NIH. Autumn, my daughter comes here. She has neurofibromatosis, also known as NF1.

(Video) Dr. Brigitte Widemann: I'm Dr. Brigitte Widemann. I'm the chief of NCI's Pediatric Oncology Branch, and I'm directing a research program directed at a disease called neurofibromatosis type 1, also known as NF1.

The trials that we have designed are for tumors called plexiform neurofibromas. They are not cancer tumors, but they can cause lots and lots of clinical problems like pain, disfigurement, motor dysfunction, airway dysfunction.

(Video) Lindsay, Autumn's Mom: Before she was born, we were having ultrasounds weekly trying to figure out why she might look a little different in my tummy. And then she was born. I'm so happy, and I can tell that the nurses are a little concerned. They kind of take her off to the side and at the end of it all they said, we don't know what's wrong, but something is.

We actually had a really great neurologist up in Kansas City. They told us that she had neurofibromatosis. He directed us to the clinical trial.

Dr. Widemann has been her doctor since she was 2 years old. We really feel like we have an advocate here that's fighting for not only Nf1 but for Autumn specifically.

(Video) Dr. Brigitte Widemann: I've known Autumn since she's been a little girl, very little, and she's always been a beautiful, energetic young lady.

When she was started on the MEK inhibitor, she had a nice shrinkage. Her tumor became smaller and her facial trauma was less disfiguring.

(Video) Lindsay, Autumn's Mom: When she's not on the medicine, it grows dramatically. So when she is on the medicine, even if it's not shrinking a ton, at least it's stable.

(Video) Dr. Brigitte Widemann: I think Autumn loves The Children's Inn. It's the place where there's a mailbox. There's a gift. I think every day, something little is there that she loves. She always has some new little friends with her, some stuffed animals. She loves the atmosphere. She's very outgoing and energetic. I believe, Autumn, one of the main reasons to come here is The Children's Inn.

(Video) Lindsay, Autumn's Mom: So after a long day at the hospital, we come back here to The Children's Inn it really feels like home when you're getting able to eat here, have homemade meals.

(Video) Dr. Brigitte Widemann: The other aspect is that patients meet other patients with NF1.

(Video) Lindsay, Autumn's Mom: We also do activities with other families here.

(Video) Dr. Brigitte Widemann: I cannot overstate how important this is because they find out I'm not alone.
(Video) Lindsay, Autumn's Mom: I know Autumn feels good about being here because she knows she's not different. Sometimes back at home. I think that she does feel a lot different.

(Video) Autumn: I made three friends yesterday. I like to find books with my mom, and today I read a cat in the hat to her.

(Video) Dr. Brigitte Widemann: The sense that they are not alone and they're all working jointly with us on identifying effective therapies with the help of The Children's Inn — that is very important and impressive.

(Video) Lindsay, Autumn's Mom: I had no idea what neurofibromatosis was when Autumn was born. So, to me, telling people what it is, is really important.

Thank you to everybody at The Children's Inn — all the staff here that has been fully supportive of us.
Wendy Harman, ClinicalTrials.gov, UX Lead: Thank you so much to Jennie Lucca for your service to The Children's Inn and for being part of the Board of Regents Working Group. We really appreciate it. That and your willingness and openness to share a couple of those real-life

stories with us today that help put in perspective exactly why we're doing this work. So thank you very much.
And hello to everyone. My name is Wendy Harmon. I'm one of the team members here at ClinicalTrials.gov modernization effort, and I have the distinct honor today to share a little bit about how we're actually using human centered methods to modernize ClinicalTrials.gov systems. We've focused every step of the way, as you're hearing today in today's meeting, on ensuring that the voices and the needs of the users are at the table with us and informing the design and development of every single piece of both the public website and PRS.

So I wanted to share a couple of top-line stats with you today. We started with the request for information, or RFI as we call them in the government space, back in 2020, where we received over 1,000 actionable ideas for improving PRS and the public site, many of them from from those of you on the call today. So thank you very much. We also interviewed over 70 people and who often use both PRS and the public website. These are representatives of data submitters, representatives of public site users. A pretty large gamut of folks. We also, as you've heard already, have gathered the Board of Regents Working Group 15 times and facilitated sessions with them to really have input and advisory comments and observations about what we're building and the directions that we should go in.

So finally, since we've made the beta sites available publicly for you all to look at, and check out, we have received over 1800 comments on, and, from all of you and my colleague Catherine, in just a moment is going to talk about exactly what we do with those comments and how we are incorporating them into the design effort as well.

I want to share a little bit about our process. So initially we synthesized all of that information that I just described to you all into a clinical trials ecosystem map to really understand the role that both PRS and the public website play in the overall lifecycle of a typical clinical trial. Everyone who touches it from the moment it's an idea, maybe on a napkin, on the back of a napkin, all the way through to the end of of the trial and results postings. And even maybe changing the standard of care for for medicine.

So, we also were able to synthesize all of this information into some findings and recommendations. But you might be wondering, how do you get from something like that a set of recommendations and findings to what you see on the beta sites today?

Well, we identified various user goals and journeys and we were able to use Agile iterative techniques to design and develop the modernized systems. This is very detailed work. We are constantly asking questions such as: What should be in the menu? How should navigation work? Where do we put these action buttons so that everyone understands exactly how to use them? What should they look like?

So we're able to design multiple concepts and prototypes and test them with real users all the way through the process. And Catherine, in just a moment, is going to explain exactly how that works.

One of the biggest challenges that we have, and we've talked a little bit about it in this meeting already so far, is that these systems are serving lots of people who have very different goals from one another and sometimes who even have conflicting needs. So even as we've focused on all of those individual details of website design, our very broad challenge is to improve the experience for every type of user without disrupting the experience for anyone.

This slide illustrates a couple, just a couple of the ways that users might have conflicting needs that we're designing for. So you'll see on the left-hand side, patients who really want search to operate exactly like Google does, and to be able to read plain language trial summaries and really understand eligibility criteria in the simplest ways. And then in the middle we have the researcher community, who is most interested in having a hyper-controlled advanced search features, and to be able to have complete scientific descriptions of the study and results. And of course, there's many of you on the call today — let's not forget our beloved data submitter community, who's really just trying to comply with the law as efficiently as possible, and doesn't necessarily have all that extra time built in to rewrite titles and descriptions that are going to meet the needs of patients in that community. So we have really kept these conflicts at the forefront of our process and tried to reconcile them in the design and in the development of our beta sites so that everyone has an improved experience.

So now that I've shared a little bit about that, I'm going to turn it over to my colleague Catherine Kihara, who's our user experience researcher, and she'll discuss with you how we use your feedback and usability testing sessions to make iterative improvements. Catherine.

Catherine Kihara, ClinicalTrials.gov UX Research Lead: Thank you, Wendy.

As Wendy said, I'm the lead user researcher on the modernization team, and myself, along with others, have the pleasure of gathering insights from you all to inform our process. So today, I'd like to walk you through how we are using your input to iteratively design and develop the public site as well as the Protocol Registration System.

We've done this by prioritizing the feedback which we received via the feedback card on the ClinicalTrials.gov Beta site. For those who have not been there recently, the feedback card is located at the bottom right of the home page. You can see it right here. It's easy to find. As Wendy shared, so far, we've assessed and analyzed over 1,800 comments, which is a great deal for us.

I want to emphasize here that we're listening. We're reading every comment and we're continuously identifying bugs and issues that you, our users, are struggling with.

Additionally, we reached out to some of you who expressed interest in participating in some form of research, providing additional input to improve our development process.

For our data submitters who are visiting the PRS Beta website, there's also a feedback channel. Again, it's located at the bottom right of the screen. It's very easy to find and we are, again, reading every comment and we're actually encouraging you to continue to give this feedback, as we are currently working to improve the PRS system. And if you would like to participate in a more focused session, you may provide an email address and we will be sure to reach out to schedule you to participate in one of our focus sessions.

In this slide, I'd like to use the search feature to demonstrate how the feedback we have received from you is influencing, or has influenced, design changes. As you can see in the Before image right at the top, we received some feedback from users saying that the color of the Search button made it hard to see. Users also shared that it was confusing to go back to the top of the form to click Search. So we incorporated this feedback and for the next release of the beta site we increased the contrast between the Search button and its background, as you can see, and we moved it from the top to the bottom of the form, making it more visible on the page, regardless of how many fields are added. My colleague Christina will go into in-depth, kind of take us through how the search has evolved. But that's a good example of how we've incorporated that feedback.

In addition to the feedback we received since 2022, we've conducted 150 moderated and unmoderated testing sessions for both the PRS and the public sites. The feedback has been used to inform and to improve the search functionality, the tabular view of the study record, and the history of changes on the public site. On the PRS we've used that feedback to improve how data submitters provide — create and modify a record. And that's just to mention a few.

I know we've heard from Jennie at Children's Inn and Wendy touched on how we're continuously trying to balance the needs between the three user groups. But here I'd like to highlight what one of our researchers said when we invited them back to participate in a usability testing session.

They said: I'm really happy that you're reading the comments. Usually you leave feedback and you never get a response. I was so happy. Honestly, reaching out to a person in two weeks, two months makes you feel connected. You kind of feel more loyal to the system and that, okay, they're working on something.

That was from a data researcher. We hear from from you, from our users all the time, and we just love reading this comments. So please, please keep them coming. For now, just like to turn our attention to the second poll question of the day.

Let's give it a second to come up. So we'd like to to hear more about how you learned about ClinicalTrials.gov Beta.

Go ahead and share that. Give it a few more seconds.

You can see word of mouth, the link on the classic site, and you can scroll down just so you can see what else we have as an option. See a majority of the people on this call learned about it from the click on the classic site. Great! I'm going to go ahead and end that poll. Thank you all. Thank you for participating in that, giving that feedback.

Again, we welcome any and all feedback. You can use the feedback card on the beta site as well on the PRS site. Back to you, Anna.

Moderator, Anna Fine, ClinicalTrials.gov Acting Director: Thank you, Catherine. And thank you to our speakers, Jennie and Wendy as well. We really appreciate your perspective on how it's incorporated and all the work that you're doing into these designs.

Next slide, please.
So I've been receiving a couple of questions and they've been wonderful. I believe it's more related to the ClinicalTrials.gov Beta website. So I think we can direct those questions when we do our breakout session. So thank you for your questions, especially when it comes to the API. I know Christine is excited to answer those and also there's been some questions regarding about Record History tab. So I think you slightly touched upon that, Catherine, and I think if you could go into the breakout room, that would be a great place where we'll address those questions. Just wanted to let you know, keep your comments and your questions coming. We are reading them and there's a good place in time for it as well.

So we're going to turn over our presentation now to our two product owners who are going to talk a little more about the ClinicalTrials.gov Beta as well as the PRS Beta. I think that's what you're all here to hear about, to come and see and learn more about. So we're very excited.

I'll introduce my first speaker, which is Christina Robinson, who is our technical information specialist. She has over 20 years of experience in clinical research and has been at ClinicalTrials.gov for three years. She currently serves as our product owner for the development of the Beta ClinicalTrials.gov website. So in this role, she's supporting the team of user experience researchers, designers, web development experts, building the modernized website. It's a whole village. It's a team. So, we know that this does not happen with just the work of one person. As a Certified, Agile Professional, she brings together the needs of patients, data providers, data researchers and other stakeholders to find solutions that work within our regulatory framework established by ClinicalTrials.gov.

So I'll turn it over to Christina so she can talk more about the ClinicalTrials.gov Beta website.

Christina Robinson, ClinicalTrials.gov Beta Product Owner: Thank you, Anna, and thanks to all of you for your time today and for being here to learn more about the modernization effort.

So I want to start with an overview of the modernization process for the ClinicalTrials.gov Beta website. So as you heard earlier, modernization was launched in late 2019 with the formation of the Working Group. That first year was really dedicated to collecting all of that wonderful

input that Wendy and Catherine continued to elaborate on. And then we spent the next year analyzing that and building out the initial version of the beta website, which then launched in 2021. So you see that here on the roadmap. We've had consistent releases since that time. They've come out from, you know, maybe every few weeks to every few months. And then later in this year the beta website will actually assume the primary URL, so when you go to ClinicalTrials.gov, you will actually see the new website and, but we will continue working on it. We have additional features to build and release. There will be refinements again based on that input that you so generously, generously provided. So please do keep that coming, in particular, once you know, beta assumes that primary URL and we release additional features.

So the bottom line for us here is that the finish line is in sight. The beta website has really taken shape over the last year and a half, and we're excited to get all of those remaining pieces out so that everyone can accomplish all of their goals on the beta website.

So this is how the beta website has evolved from the user perspective. You can see again here that it launched in December of 2021. We've continuously released and made improvements throughout that time frame, and the primary, the beta website will actually become the primary experience in June. So just right around the corner, honestly. So when you go to ClinicalTrials.gov, that's what you will see. But I want to point out, as you see here on that fourth, in that, just under that fourth circle, that the modernized ClinicalTrials.gov will not be the only site; it will, the classic site will actually continue to be available in parallel. So once you go to ClinicalTrials.gov, if you want, you can actually return to the legacy system. And we'll obviously continue to make improvements to ClinicalTrials.gov for the life of the product.
So what you see here is an image that actually gives you some insight into our processes, sort of behind the scenes. In the top left-hand corner, you can see the classic ClinicalTrials.gov and then all of that valuable input that we got, in particular, in the early years of modernization, but that, you know, we'll continue collecting indefinitely. We've got, you know, we've got our design process where we analyze that input and we check it against technical feasibility before we consider that finalized and ready to actually build. In develop process, you know, they ask for clarifications from the designers; they do, you know, any testing necessary. And then we actually deploy for all of you to see and provide feedback and that user feedback and analytics there in the bottom right-hand corner is really important because that continues to inform our processes. So the loop just starts over again.

Now I want to take you through the evolution of the search functionality that we have on the beta website. As you see here, we have the classic ClinicalTrials.gov. And we know that, you know, the search feature, the search functionality is really, really crucial. That is the primary reason for coming to ClinicalTrials.gov, so we want to make it the best that we possibly can.

When we launched in December of '21, this is how the beta website looked. And I just want to point out a few of the key features, starting with the fact that we have optimized for mobile throughout the process. We do have, you know, folks accessing ClinicalTrials.gov on mobile devices, and we want to make sure that it's easier for them to do so than it has been previously.

So a couple of the other things that I would point out is that we have throughout this process adhered to the United States Web Design System, principles for design. You can see that in the top left-hand corner there that this website is designated as an official website of the United States government. It's identified additionally by the NLM logo and the ClinicalTrials.gov logo.

Over on the right-hand side, you can see that we have a streamlined site menu that'll be built out as we continue migrating content and building out new content for the beta website.

The big blue banner here you see across the middle is a welcome banner. One of the things that we've known for some time is that a very large portion of our users — close to half in fact — when they come to ClinicalTrials.gov, it is their very first time on the site, and so we have what we call here a welcome banner so that they would know, you know, where they were and what they could do here.

And then in the search form itself, we wanted to give users the opportunity to look for all studies, studies that were looking for participants, or studies with results. And again, that's based on that user input; we know that the vast majority of the public and patient group users are looking for a study either for themselves to participate in or for a loved one or friend. But, you know, obviously there are folks who are more interested in the studies with results.

And then finally we had a simplified keyword search field where you could enter any number of things to narrow your search. And again, location, because those folks who want to participate in a study are hoping to find one near them. For the location we've actually integrated the Google Maps API so that the location search functionality is a bit more precise.

We had in the summer of last year, planned on doing other work, but because the input that we were getting from all of you said that advanced search was so important that we needed to get it on the website right away, that's where we focused. So you'll see here that we added an action bar across the top of the search form, where you can select additional fields. This allows users to customize the search form, add all fields, or reset to default. When you do select fields, when you click that button, you'll get a modal, and you can then scroll through this list of criteria; you can pick any number of things to narrow your search.
But, as Catherine mentioned in her section, the Search button was tough to find, and it was at the top of the form, which just didn't make sense to a lot of users. And so we moved that to the bottom of the form. We also took away that big blue banner because we were hearing that while it was nice to have, it was in the way. The point of the website really is to find those studies that you're looking for and and folks want to get right to it. Again, we moved the Advanced Filters button and the Search button to the bottom of the search form, and as you scroll through the form, that bar, that action bar will follow you.

Finally, we wanted to confirm, because we did hear, you know, in the formative research done early in the process that users wanted, you know, a Google type search where you could just enter all of your criteria, hit Enter and go. So we wanted to make sure that users, that the

keyword field that we had initially on the Beta ClinicalTrials.gov wasn't the right way to go. So earlier this year we built a prototype and did extensive usability testing. In fact, we recruited several users based on those comment cards and feedback that we had gotten with contact information, so that we could make sure that this wasn't the right way to go.

I just want to also point out quickly that there is a short disclaimer at the bottom of the form, and it's been there all along; so even through those previous iterations of the search that we saw, it was there, but it was at the bottom and so folks weren't using it. And when we did this usability testing, we asked for additional input here. And while users said, Hey, this is great information; it's really important, so we want to see it top and center; it's a little too big and it will get in the way.

So this is the search form that we have designed now and are currently building. You'll see that the disclaimer is at the top of the form, and we made some enhancements to the form. So users told us that they really do prefer the default search form with some, you know, some options for narrowing their search. We added Intervention and Treatment, which doesn't exist on the classic website. We streamlined the Location that previously was, apparently, really confusing to have the option to search for a particular location, or by city or country or state.

And again, users do want to see the — apologies — do want the ability to narrow the search to studies that are actively looking for participants.

So this table shows a summary of all of the work that we've done to date. Everything across the top in the green section is already done. You can see here we have some additional work in progress. The next iteration of the search. We're making some additional changes to the Record History, information architecture, and so on. And then there's more work still to come. We know that XML download is really important for certain users and we will finalize the API. We want to find a more modern replacement for the RSS because, again, we know that it's really useful for our users. And, again, for the patient group connections to trusted health information and the next steps to join a study because that's really their purpose for being on ClinicalTrials.gov.

So to summarize quickly: the new website will be the primary website in June of this year, but the classic website will continue to be available.

With that, I actually want to introduce my colleague, Dr. Nachiket Dharker. He is the product owner for the ClinicalTrials.gov PRS modernization team. He's been with ClinicalTrials.gov for 10 years and has supported the program in multiple roles as part of the results, registration and modernization teams. He has a master's degree in genomics and bioinformatics from the George Washington University, as well as a PhD in molecular neuroscience from George Mason University. Dr. Dharker.

Nachiket Dharker, PRS Beta Product Owner: Thanks, Christina. Hi everyone. I'm very happy to share the updates on PRS Beta with you all. So this is the strategic roadmap of the PRS Beta at

a high level. We launched the PRS Beta site in February last year and when we released the Record List for the first time, and since then we have been continuously making updates to the system. We first enhanced the Record List by adding additional features for the administrators, allowing them to better manage the study records within their organizations. And since last fall, fall of 2022, we have focused towards developing the protocol registration system or the protocol registration section, sorry, that allows users to enter information for their study protocols, within the PRS.

Since the protocol registration section has a lot of dynamic fields and dynamic screens and involves validations across different sections within the Protocol Section, we decided to release the protocol registration as a single release in the PRS. However, we are releasing constant updates on the PRS Test site, as we are building protocol registration, on a regular basis. The PRS Test site is a sandbox environment that mirrors the PRS Production site. The important features of the that we still have to complete are the quality control review process and the result submission.

So from the perspective of our users, how they are seeing the PRS Beta being developed? As already said, the PRS Beta was launched in early 2022, and since then we have been adding features to the new PRS on a regular basis; and we will continue to do so until all the important features of the PRS are implemented in the beta system, at which point we can make the beta system the primary site. After that point, we will continue to add more features and also continue supporting the legacy system, and towards the end, when all the features have been modernized from the classic PRS to the new beta site, we will retire the legacy, and at that point the PRS Beta site will be the only site that the users can can interact with. And that, from that point onwards, will then enter the stage of continuous improvement, meaning we will continue making improvements once the basic modernization is achieved.

So next, I would like to take the opportunity to orient you to the new Beta PRS. Currently, PRS Beta can be accessed within the legacy system, meaning once you log in to the classic site, the PRS application, you will be taken to the classic Record List or the Record List within the classic system, and with, just above the classic list you have the button here that the users can use to click to access the beta system. For the purpose of this presentation, I will not focus on the Record List. In the previous webinar, I had provided an overview of the PRS Record List in detail, and that recording is available on our ClinicalTrials.gov public site, and we have also provided a link to the site, to that recording here.

So this is, once you click the green button to access the beta site, you will be taken to the Record List in the beta format, and as I just said, this is the link that you can use to view the recording of our previous presentation.

So on the new Record List, you will see the two open options to open a record for each, within each row. The first Open link will open the record in the classic format or will open the record in the old legacy format. The Open in Beta link will open the same record in the beta environment.

In the classic system, the landing page when you open a Record List is called the Record Summary page. And we are thinking of maintaining the same architecture on the beta site. Currently, this page is under development and since it will pull in information from different parts of the study record, it will be continuously updated throughout the cycle, throughout the project. And as I noted earlier, that we are regularly releasing updates to the PRS Test system, and the, you know, the protocol data entry screens at this time are available in the test system. However, with the release that we are going to have in May to the PRS Production site, users will have the opportunity to enter the data for the protocol registration, or the protocol data entry, in the new beta system.

So on the screen for record summary, you will see a horizontal navigation. And in order to view and enter data for the study protocol, the users will have to click on the Protocol tab here on the horizontal navigation. And once you click the Protocol tab, it will take you to the Protocol Section. And this is just a visual of how the section looks like, looks like at the present, at present.

We have a left navigation, that menu that includes all the protocol modules and that you can use to simply, you know, you can click, go through the different modules.

Sorry.

So by just selecting different modules on the left pane or left menu menu, you can view, not only view the data in that section, but also you can update the data or enter the data on the same screen. So as you can see here, we have attempted to flatten the navigation in the PRS Beta, compared to the navigation system — sorry — compared to the classic system, where you had to go back and forth between the main screen and the protocol summary page and, in order to enter data for the individual sections within the Protocol Section. And this was done based on the feedback that we received from our users who, you know, really wanted us to improve the overall experience in the PRS Beta.

Another improvement we have made is, in the PRS Beta, is based on our users feedback, is introducing just-in-time help on every screen. We have added more on screen content to help our users enter data into the system, and we have also created a Help Drawer that pops out from the right of the screen when a user clicks the little "i" icon next to each data field. The Help Drawer includes three pieces of content. On top there is a brief guidance provided provided about the data field.

Then there is additional information in cases where we felt that we could, you know, users may need additional guidance about the data, data field or what they need to enter. And at the bottom there is a link to the data element definition as well as the data element definition noted on the bottom of the drawer. The brief summary, as well as the additional information is, will be in the plain language.

So this was how we, you could open an existing record in the PRS Beta and work with the new protocol registration screen by using the Open Beta link that I showed you on the Record List. Another way to access protocol registration from the Record List is to create a new record, and this feature is provided within the Records menu on the top right side of the Record List page.

Selecting this option would allow you to create new record, and the first steps to create a new record are pretty same as how they are in the classic system currently.

So that was a brief orientation on the newly added screens in the PRS Beta. As a quick recap, the protocol data entry screens are currently available in PRS Test environment. In early May we will release the new screens to the PRS production site. I would strongly encourage all of you to test the protocol registration section and provide your feedback using the feedback button on the bottom right of the screens. If you notice bugs or any issues, or if you notice that your records are displaying inconsistent information between the legacy system and the new system, please definitely inform us because we will take a look at each of your comments and, you know, take a deeper dive and see what those issues are about. And while providing the feedback, we would also strongly encourage you to provide any context that you can provide us, for example, the protocol ID or the study title, etcetera.

So in the next few months, we will continue to resolve issues that we encounter in the protocol registration section, and we'll also add additional features that we left out of from this round. We will also move forward and update the record summary page in the next few months. So you will notice changes to this page, you know, in the coming time. And when we will move to and then we will move to the protocol QA/QC, and then at the end of which we are hoping that our users will be able to submit the record in the new system and then we can provide our users the Review Comments in the new system. After that point, we will move our focus to the result submission and the results QA/QC. So a lot of work still needs to happen with the Beta, as you can see, and we will keep you all informed about these improvements.

Thank you. With that, I will pass it back to Anna.

Moderator, Anna Fine, ClinicalTrials.gov Acting Director: Great. Thank you, Dr. Dharker, and thanks again to Christina Robinson for providing the overview on both the ClinicalTrials.gov Beta and the PRS Beta.

And I did receive a question, I believe from Morgan, asking for the link to the site. So you'll see our moderators dropping those in. I believe you're asking for the PRS Test site, so feel free to chat me if I got that wrong. But we'll drop the links to all the Beta sites so you know where you can find them.

So thank you again for all our presenters, and kicking off our meeting, and providing us a great overview and how all this commentary and feedback has been received and incorporated, and giving a nice orientation to where we are today with our betas. Now that is just a nice little snippet orientation to both of our sites. If you'd like to hear more about one of these products,

both Miss Robinson and Dr. Darker are going to be leading breakout rooms. We'll be starting those breakout rooms at 2:00, so we'll be taking a break in just a few minutes. You may choose the room that you'd like to enter. I'll describe a little more about the rooms as you try to make this decision. Hopefully you won't have FOMO, but don't worry, they are both going to be recorded. So when the replays are available sometime in May, you'll be able to go back and hear what happened in the other room where you might have missed out.

So room 1 will have a presentation from our Board of Regents member Dr. Woloshin, who will describe his experience using the ClinicalTrials.gov Beta — the good, the bad, what he likes, what he doesn't like — and we'll be responding to that, like why certain decisions were made the way that they were, what we still have work to do and where we could do better. So that'll be the breakout room one to hear more about ClinicalTrials.gov Beta. Those that have been asking me questions about APIs, that's probably the room you want to go to as well. Christina Robinson has a little more insight on the beta API and some timing on that, so that's where you can ask some of those questions. And did already pass them on to our moderators, so I'm sure they're ready to answer those for you.

And then in room 2, we will have Dr. Carrie Dykes from the University of Rochester doing a presentation with her experience using the PRS Beta.

So next slide, please.

We will have a presentation from Carrie. She'll be sharing her experience, and then Dr. Dharker will be sort of responding to that, and of course, we'll have moderators in that room.

The chat will be open in the breakout rooms, meaning you can chat with each other or chat with us, chat directly with the moderators. So it'll be the place where we can have a little more interaction. We do have almost 500 participants, so you can imagine it's hard to kind of unmute people or have open chat during this main session, so this will kind of break out folks into smaller groups. So those are the descriptions of the breakout rooms.

Let me get you a description how to get in. If you already know how to get in, take your break, come back at 2:00 and no worries. This is a nice time to think about your questions. Maybe go play with the beta site and then join us in the breakout rooms.

Like I said, both rooms will be recorded, so if you have difficulty choosing one, you'll always be able to see the replay when available. At the end of the breakout rooms, we'll come back here for just a little recap before we wrap up the meeting. The rooms will begin promptly at 2:00, so it's okay to take your break now. And you can either enter the room now as they are opening or when you come back from your break, feel free to choose the room that you'd like to go into.

If you return back from break and having difficulty again, you can message tech support. After a few minutes, if we find that people were not able to successfully join rooms, we're happy to

just put you into a room, so don't worry. Now to enter the rooms, you're seeing it at the bottom of your task bar, and you're either going to be seeing where you see here in the image, the breakout rooms, or you'll see the dot, dot, dot for more, that might be on some people's screens and browsers, how they're seeing how they can enter.

So please enjoy the break and we look forward to seeing you at 2:00. So right now you will not be hearing any audio. And again, we'll be back in the breakout rooms at 2:00. So thank you.

Moderator, Anna Fine, ClinicalTrials.gov Acting Director: Right. All right. I think officially we have everybody back. So thank you. Welcome. Welcome back to the main session.

And thank you to our moderators and speakers who were put on the spot taking your questions and trying to answer all of the feedback that you're providing us. We really do appreciate it. Again, it's extremely helpful. I'm going to ask someone to please advance to the next slide.

Thank you.

So the breakout rooms again were recorded. So the recordings and slides from both rooms will be made available sometime in May; we'll make sure to announce that.

It sounded like highlights from room one, I understood from Christina, when dropped into some of the rooms, people are definitely asking about some of the features and which features are going to be on beta, especially some of the features that they're used to using in classic. So I did hear Christina having to reassure that if it's not available on beta, don't worry; you'll continue to be able to use classic until we see that most of the desired features are available on beta, we will not be retiring classic. So I think that's really important and I'll recap that in just a second again.

And then highlights from PRS Beta room, again, talking about features; someone asking how to gain access so they can start seeing PRS Test and as all the releases are made available there right now before it's available in PRS, which will be in early May. It sounded like some questions about automation. I would love to be able to just upload my document and be done. That does sound lovely. I'm not sure that we're all quite there yet, in the technology there, but that's great feedback. And then I did love seeing that Carrie pointed out some features she'd like to see, especially when it came to sorting by alpha and such, and I love seeing that in the chat people just echoed, Yeah, me too. So love that you're the voice for the community, Carrie, appreciate all the feedback that you gave us during that session, and thank you to the others that chimed in, because it is helpful, you know, when you kind of upvote things, and we see, Oh wow! This is overwhelming. People really want this. So let's start prioritizing some of it. So it's really been helpful to to see that as well.

Next slide, please.

So thanks again to the moderators and to the speakers. To recap from the meeting, as well as from the meeting rooms, and just making sure that some of the main take home points here are that, in June, the website, the beta website — if you haven't seen it yet — will be your landing page. It will be the primary website. And the classic site will continue to be available; we're not going to take anything away. So we're allowing people to use the beta website. You're going to have a banner at the top on the beta site that you can still go back to classic, if that's what you prefer and that's what you're used to.

And we're going to be monitoring that; we're going to be seeing what the traffic is. We're monitoring now what the traffic is between the two sites. How often are people going back to classic? What are they going back for? And, you know, making sure that that's part of our decision making. So it won't be any time this year that the classic site will be taken away. And perhaps sometime next year, and we will, of course, be announcing that; we will give plenty of warning. Let people know, hey, looks like everyone's liking the beta. And so don't worry, we'll give you warning when we think that we'll be retiring the classic site.

Now, of course, we can't manage two websites in perpetuity. And of course the questions do come, and I think some of these questions came up in PRS as well. What's the source of truth at some point, right? What if there's something different in one site versus what I'm seeing here? Or what's different on classic versus on beta? You know, you're not going to want to have two main websites and you'll want to have just one, so we'll be working towards that based on your feedback and the features that we still need in beta.

Next slide, please.

And so also for PRS Beta, you can see the new registration module in the PRS Test at the moment. If you have a PRS test account, you're able to go in there and you can start playing around with it. That's how Carrie did her assessment of it. But in May, in just about a week or two, you are going to be able to access it in PRS, and you'll be able to start using it and entering your record in that way. So we just want to make sure that you took that take-home message that there will be an announcement that this registration module will be in PRS in just a week or two. And you'll still be able to do it the old-fashioned way, the good old classic. So, you know, don't worry. You have the option to start entering your record this way, or you can also continue to do it in classic. Now, I do believe Nachiket did underscore because it is still beta, we know that there's probably going to be some kinks and some challenges. And so you're not going to be able to fully submit it in the beta. You'll have to go back to classic to hit the submit button. So just wanting you to be aware that we are aware of that.

We want to give this a couple of months, get your feedback, get people using it more because people obviously can't be using it in PRS Test now. So just want you to know, please continue to use that feedback button. We do anticipate you will see some bugs and issues, but please do try using it because the only way we can resolve it is based on your usability and getting that feedback from you.

Now this is on its own timeline PRS is going to continue to have more features built. We're going to be focusing on results, at some point the QA/QC. So PRS is going to be still going well into next year before you'll even start to see some of those modules. Just wanting you to be aware about that. And we will not be taking away the classic PRS, At least another year or two. I know people keep asking us for timelines. We base timelines on you and your feedback and how we're making sure that the system works. We're not going to just put something out there, shut it down and say, There you go. Here, you have to live with it. We definitely want to continue to make improvements and make it as optimal as possible before we get to those types of points, and absolutely communicate around it.

Next slide, please.

So communication, as you've heard, has been always at the forefront of this. We have a wonderful Working Group where we can leverage expertise, such as from the members you've heard from today. In one of the breakout rooms it was from Dr. Steve Woloshin, and also in the other breakout room from Dr. Carrie Dykes. They are the voice of some of the communities, and so we really appreciate that. We're continuing to meet with the Board of Regents throughout this year. And then we also are continuing to consider how we can best engage you. So in just a second, we'll be doing a poll. But we're doing social media; we're leveraging that. You know, we tell you to sign up for our Hot Off the PRS! That is our main way of being able to put some messages out. If you want to know about the details of each release, why features were added, when they were added, and the timelines, that's all in the release notes. And of course we said we're going through feedback comments, continuing to do interviews, and talking to people one-on-one. It's all part of the process. It's very important to us.

So I'd like to go to the next slide because it's really important to us to hear from you before we wrap up this meeting. How do you want to stay informed? What would be some good options? And could we also, I know the polls open, but can we also go to the next slide, as well?

What works for you? You know, we've done webinars. We try to do at least one per year. We do blog posts. We know that there, we have colleagues across the pond that do office hours. So we're thinking if that's an option, so we can take your questions or talk about a certain feature that might have been released recently and kind of dive through it a little more. Training sessions.

So please, I think you can also scroll, if you aren't aware, in the poll itself. Yeah, I see that you are seeing it. Meetings like this are important. Bulletins are important. Let's just give it about another 10 seconds, because only about half of you have participated in the poll so far.

So this feedback is important. So we continue to make sure that we do meetings like these, or webinars or whatever it is that you think works best for you. What's hard, though, from what I'm seeing — and we're going to end the poll now, and I'll share the results so everybody can see them.

The predominant is you love the Hot Off the PRS!, so love that, and people are happy with a meeting like this, so that's good to hear. Those are sort of the, the top front-runners, and webinars. So it does sound like our efforts to have meetings such as these are helpful. So I'm happy to hear that. So that's important. We'll continue to do that. Thank you. Thank you for your feedback on that.

Okay. And we'll go to the next slide.

So we have next steps. Our next steps, of course, are to announce the meeting recording and the slides. They will be available. Of course, we want to make sure they're closed captioned. They're 508 compliant.
So it does take us a little bit of time to download the transcript and make sure that all the materials and the videos and everything are available. So please bear with us. But we usually try to do it within a month. So you'll hear that through the Hot Off the PRS!.

The protocol registration forms are going to be available in PRS. It's just going to be in the next week or two. So you'll be hearing about that in the Hot Off the PRS!,and same thing with ClinicalTrials.gov Beta will be primary, so that will be in June, and we'll be announcing that, and we'll probably have some technical bulletins around both of these announcements, just so you're aware.

And for you you have a homework assignment: Continue to provide your feedback. Use the betas. Give us your feedback. Bear with us. They are called beta for a reason. We do acknowledge that they are not perfect yet, but we're hoping to get there, completely based on your input. So thank you.
And with that, just a reminder, if people don't know how to sign up for Hot Off the PRS!, we have a link here, and I'm sure someone, one of my moderators could also drop it in the chat.

We do have one web page, and this, this is good feedback we actually received from our Board of Regents. We have a web page about modernization, because when we first launched modernization, we had nothing else to point to but our own classic site. And that is the source of all materials to date, including the release notes on that page. But when we were releasing sort of tutorials on how to use the classic website or PRS. It was interesting, one of our Board of Regents members had said, Why would I go to an old website to learn how to use your new website? So that was really good feedback. We'll make sure that we incorporate some of the materials and content in the future on the new website as well. But right now, because that's our source of truth, that's where all content is. So that's the link to this modernization site.

And, again, for those who are looking how to get a PRS test account, or had some questions on things that they're seeing in PRS, issues with their personal records, I saw there were questions about that, you can always contact us at register@ClinicalTrials.gov. But otherwise, thank you so much, everyone, for the input, for the interactivity, to all our speakers and all the teams behind this. We really appreciate the time that you took to spend with us this afternoon, and this concludes today's meeting.

I hope everyone has a great afternoon. Bye bye.