Coordinator: And hello, everyone and welcome to Research & EHR Synergy, a cyber seminar series hosted by VIReC, the VA Information Resource Center. And thank you to CIDER for providing technical and promotional support.

Research & EHR Synergy is produced by VIReC in conjunction with the ORD Strategic Initiative for Research & EHR Synergy, OSIRIS, and the VA Coordinating Hub to Promote Research Optimizing Veteran-Centric EHR Networks, PROVEN. And it focuses on helping the VA research community stay informed about the EHR modernization.

This series is held on the fourth Wednesday every month at 12 PM Eastern. You can find more information about this series and other VIReC cyber seminars on VIReC's website; and you can also catch up on previous sessions on HSR&D's VIReC cyber seminar archive.

A quick reminder for those of you just signing in, slides are available for download. This is a screenshot of the sample email you should have received today before the session; in it, you will find the link to the download for the slides.

Today's presentation is A VA-Focused Introduction to Cerner PowerTrials, and is presented by Ashley Morris and Mary Schooler; and Drs. Lindsey Jarrett and Maria Souden joining as discussants.

Ashley Morris began working with the Current State Impact team in October 2019 as a project coordinator; prior to involvement in the CSI team, she worked as study coordinator in R&D at VA Puget Sound.

Mary Schooler began working with the Current State Impact team in January 2020 as a project coordinator. Before that, she was with AmeriCorps VISTA in South Carolina after her graduation from Duke University Masters of Global Health program.

Dr. Lindsey Jarrett is a social scientist dedicated to clinical research and currently is leading research strategy at Cerner for their government service line; Dr. Maria Souden is Director of VIReC and, along with her other duties, Maria serves as the lead of the National Research EHRM Research Subcouncil advocating for researchers needs in the Cerner implementation.

Thank you all for joining us today. And Ashley, can I turn it over to you?

Ashley Morris: Yes, thank you. So, I am Ashley and I’m here with Mary, and we are on the Current State Impact or CSI team. And so, the CSI team is a local team that's working on the Cerner implementation, and so our team is focused on assessing the on-the-ground impact to research at local sites and then assisting research at each local VA site as they go on that transition to the Cerner EHR.

So, in today's session, Mary and I will walk through Cerner's research application, which is called PowerTrials, and so we'll be showing some of the application features, and we will briefly discuss which types of projects can benefit from using PowerTrials. Not every research study will need to use PowerTrials or need to use all these applications, but we'll discuss which studies could benefit from it as we go through today's session.

So, to start, we'd like to get a bit of a sense of our audience today. So, we're curious what is your role in research and the quality improvement process, if you're an investigator, PI, Co-PI, a statistician, data manager analyst or programmer, a project coordinator, or other? And if you are "other", please describe using the Q&A function.

Coordinator: Alright. And those answers are streaming in; we'll let that just run for a few more seconds before I close out of it. Folks, please remember to hit "Submit" after you select your answer choices.

Alright, things seem to have slowed down quite a bit, so I’m going to go ahead and just close off the poll and share the results. So, 13 percent said A; 16 percent said B; 19 percent said C; 23 percent said Other, D, and some of those are clinical operations, RA, research supervisor, and council admin. Back to you.

Ashley Morris: Thanks. So, it looks like we do have quite a few researchers or people involved with research. So, hopefully, some of this will be useful as we go through what research may look like after the Cerner transition at your site.

And so, we are going to go on to the second poll question about how many years of experience you have working with VA data. "None, I’m brand new to this," "One year or less," "More than one, less than three," "At least three, less than seven," "At least seven, less than ten," or "Ten years or more."

Coordinator: And so, again, answers are coming in; we'll just let that run for the next few seconds to collect our answers, and then I will share the results with you. Alright, it seems like things have slowed down quite a bit. So, we'll go ahead and just close that poll and share the results. So, 5 percent said A; 7 percent said B; 9 percent said C; 17 percent said D; and 15 percent said F. Alright, back to you.

Ashley Morris: Thanks. And so, for today's session, we won't focus too much on data, but there will be some data pieces that we will highlight, so some changes about data that might be relevant for research. So, this is a look at the overall deployment timeline for the Cerner EHR and this is divided by VISN, so it's a ten-year timeline overall. The first site went live in October of 2020 and that was Spokane or Mann-Grandstaff in Washington State. And so, Spokane went live with an initial capability set; there were some specialties that are not provided at the Spokane site, so those specialties weren't included in that initial capability set as it was a smaller site.

And so, the first big medical center with that second capability set with some specialties will be Puget Sound or Seattle, and the anticipated go-live for that site is September, and that will be followed closely by Portland, Oregon. So, the first two VISNs going live we'll be VISN 20 and VISN 10; and so then looking at this timeline, you can kind of get a sense of when the transition may be coming to your site. And when your site begins implementation, your site will be getting guidance both from Cerner teams and from VA teams to help your site work toward that transition.

This is another deployment rollout schedule; this one is looking specifically at the next two years, so 2021 and 2022. So, with this list, the yellow shading is a VA site that has some research and the green shading are those sites that have a large research presence. So, the next site that's anticipated to go live that has research is Columbus in Quarter 2 of this year; and then, as I mentioned, the kind of first two big large research VISNs going live will be Puget Sound and Portland in Quarter 4 of this year. And then, after that, there'll be a little bit of a break and the next VA site going live anticipated will be in Quarter 2 of 2022.

So, for our session, the next piece that we'll go through to kind of start us off is that we'll do a quick overview of the Cerner EHR and some of the language that Cerner uses to create a kind of base knowledge as we then move forward through the session. So, we'll start with the different Cerner platforms. So, the first Cerner platform is the one that we will spend our time talking about which is Millennium; so Millennium is the Cerner EHR, it's made up of different applications and those applications usually have "power" in the name, so like PowerTrials; and so we'll spend most of our time talking about Millennium and the different applications. But another application is HealtheIntent; it can receive data from multiple EHRs and data sources, and it can aggregate, reconcile, and transform data. And then the other platform is CareAware which is device connectivity.

And so, going back to Millennium, with some examples of Millennium applications--and these are the Millennium applications that we will be talking about later today. And so, first is PowerChart which is comparable to CPRS, that's the medical records, that's the patient chart, that's where orders are placed, that's where documentation is written; and then another application is PowerPlans which are orders and order sets. And then kind of the big application we'll be talking about today is PowerTrials which is the research application. And so, it's got study administration, enrollment, recruitment kind of all of that research focus is through PowerTrials.

And so, one of the strengths of the Cerner system is integration; Cerner applications integrate with one another and communicate with one another. And so, one way that we tend to think about it is that Millennium is kind of similar to Microsoft Office Suite, it's a suite, but the suite is made up of all the different applications like Word, Excel, or PowerPoint. So, while there are different applications that you use for different purposes, they are all part of Microsoft living within that overall Office Suite, so all the power applications are living underneath that overall Millennium umbrella or suite.

And so, this is a visual representation of--well, I just went over on the previous slide. So, the overall--and we will be showing this visual quite a bit throughout the presentation-so, the overall, we have Cerner Millennium, and we have it here divided by the clinical setting and the research setting. So, in the clinical setting we have PowerPlans and PowerChart, so these applications are the ones most likely to be used while you're with a patient. So, you're sitting with a patient, you open PowerChart, you open their record to place an order, to write a note; you use PowerPlans to place an order on that patient.

And so, then, in comparison, we do have the research setting. So, this is PowerTrials and the PowerTrials sub-applications. So, you're less likely to pull up PowerTrials while you're with the patient, it's used for things like recruiting patients, tracking enrolled patients, updating the study staff list, not necessarily something you do in a patient appointment, but something you might do more in that research setting.

And, as I mentioned, all of the applications integrate. So, any change in PowerChart--if you enroll a patient in PowerChart, it talks to PowerTrials, so that patient's enrollment would appear in PowerTrials and all of that; that's where all of the applications are sharing information and talking to one another.

So, we'll start with a quick overview of PowerChart; and as a reminder, PowerChart is the medical record and used both clinically, obviously, and then also for research. So, we're back to this visual of the organization. And so, when we talk about PowerChart, so the medical record to replacing CPRS, that's most often used in a clinical setting. So, this is a screenshot of PowerChart, the new CPRS, so this is what you would see if you pull up a patient's record. So, along the top banner here is patient information, so whose record are we looking at; their names, basic demographic information; on the left-hand side here, we have the tab menu so we've got tabs like orders, diagnoses, notes, problems, similar to some of the divisions in CPRS or JLV.

And for research, for this session, we'll focus and point out this clinical research tab. So, this is a dedicated space in the record for research enrollment history; so, this would be used for--if I am a clinician, not part of any research study; I’m a primary care clinician, I’m with my patient, and I’m curious to see if they're on a research study, I would navigate to this tab to see if they're on a research study or if my patient's research participation has ended.

Mary Schooler: So, this is a closer view of that Clinical Trials tab that Ashley was just talking about. As a clinician, as she said, I would come here to see what's going on with my patient as far as a study is concerned. So, the first thing I might see is the protocol name; this is going to be the study mnemonic with the facility number and IRB number. The next thing I might see is this contact information section; this might be the contact information of the PI, or study coordinator, or some other study staff. If I really have a burning question that's not answered here, I can go ahead and contact them using this information.

But really, where I’m going to find the most information about the study is going to be in this red section; this is where studies can upload information that's going to be helpful to me as a clinician. So, this might be a short summary of the study such as an abstract, drug info, if there's any investigational drugs or things like that. So, if none of my questions are answered in this section, then I might go back to that contact information and reach out to them.

The final thing that I’ll see here are these three dates. So, the first date is the on-study date, so it just lets me know that this is the date that my patient was enrolled; the next date you're kind of going to see at the end there is the off-study date, which means that my patient is no longer on that study, this information is not necessarily pertinent to me as their clinician anymore. And then this middle date, this off-treatment date, this tells me that there was a treatment and they're now in follow-up. So, any drug information is going to be important; however, it might mean that they're off that treatment and they're just being in follow-up, so I might want to be out looking for adverse events and things like that depending on what these dates are entered here.

But again, information on the Clinical Trials tab is geared towards a clinician and any individual not part of the research study; so, it's not going to be where you track all of your study information; this is for an outsider to the project.

Ashley Morris: Alright. So, that was a quick introduction to the medical record. And so, our next piece that we'll talk about is PowerPlans, so those are the orders or order sets. So, back to this visual organization, so PowerPlans are the other clinical setting piece used for ordering and PowerPlans are used for both clinical orders. So, we do have another poll question: if you are in research, does your current study or studies place orders on patients? So, we have, "Yes," "No," or "Not applicable."

Coordinator: Alright. So, that poll is now open. Again, the question is does your study place orders on enrolled patients and the answers are, "Yes," "No," or "Not applicable." Please remember to hit "Submit" once you select your answer choice, and we'll just let that run for a few more seconds before we close it out.

Alright. So, it seems as though things have slowed down, so I’m going to go ahead and close that poll and share the results. So, 14 percent said yes; 13 percent said no; and 19 percent said, "Not applicable." And back to you.

Ashley Morris: Thanks. So, it sounds like there's not a huge percentage of folks here that have studies that place orders, but there are some, so this will be very relevant for those folks. So, just an overview of PowerPlans. So, they are protocol-based order sets, so they are plans that are created for each study specifically and they're used to place orders on PowerChart on enrolled patients; and so the current state analog for this would be any order that's placed through CPRS would now be placed using PowerPlans. And PowerPlans facilitate research billing; so, on the back end in the system, PowerPlans allow for the attaching of a research account so that when the order is placed, the charge for that can go to the sponsor or whoever needs to be billed for that charge, so it can automatically get directed and invoiced out to that sponsor or entity.

So, we are back here in PowerCharts to the medical record. So, PowerPlans are accessed through PowerChart. So, if I am a clinician researcher and I’m sitting with my enrolled patient and I want to place an order, I would have their medical record open here, I would navigate to the Orders tab, which will be the same place where I would go if I were placing an order on a patient who is not in a research study, and once in the Orders tab, I would look here under plans and I would see all of the PowerPlans that are associated to my patient and that I could place on my patient. So, again, with the integration piece of Cerner, once a patient is enrolled on a study, all the PowerPlans associated with that study will automatically appear here in their record as a power plan that I can order on the patient. With our screenshot that I have right here there are no plans listed here; we couldn't get into the domain for a screenshot of a research power plan, but right here under this order is where it would appear.

And so, I can also search for my research power plan name if it's not appearing; the power plan name will just be the study name, so this search ability can be useful for studies that place Orizon patients before enrollment. So, if a specific order or a specific result is part of my study's eligibility criteria, I may need to place that order before my patient is enrolled on the study, so the power plan wouldn't automatically appear. I need a certain MRI results, so I could manually search for my power plan, it would be my study name, and then I would pull it up and place that order.

There are guardrail options in these situations when these orders are getting placed on patients that aren't enrolled on the study; you can file those orders or you can block them. So, they're called hard or a soft stop. So, a soft stop is when it's knocked on a power plan, when I go to place that MRI, a pop-up will come up saying the patient isn't on an academic study, I have to acknowledge that pop-up; I give a reason, I write my name, "I’m the clinician-researcher, it's for eligibility criteria," and then I’m allowed to place that order on the patient even though they're not involved in that study. With a hard stop, when I go to place that MRI order, the pop-up will say that the patient has to be enrolled; I won't be able to place that order, I will have to enroll the patient into the study and then I could use that power plan on the patient. So, hard and soft stops are decided on a steady by study basis, but it does give the study some control over when the orders can be placed and if the orders can be placed on patients who aren't in the study or you will require those patients to be enrolled on the city before any of those orders are placed.

Mary Schooler: So, this is a closer view of a power plan; the power plan example here is not specific to research, but they basically look the same, so we'll just go over some of the main points here. So, if I am going to order this power plan, I’m on my patient, I’m going to see here, in this left-hand column, my power plan name. If this was a research plan, you would see the "RES" in front of it as well as your study name. Now, under here, if this was also a research plan and there were multiple visits, you would see those under here. So, some examples of a visit name might be a pre-screening visit with all the pre-screening orders, or a follow-up visit with all the follow-up orders. So, I would be able to click the specific visit I wanted to order from this column right underneath the name of my power plan.

So, once I select the applicable visit, I’ll be able to see all of my orders that will be included on the power plan here. So, the first thing we'll see is the name of the order, and then we'll see a detail of the order. So, this is usually fairly filled out by the study beforehand in order for the power plan to be built into the system. As a clinician, I’m going to want to make sure that I review this and add any other details that are needed based off of the patient's needs and the protocol; but something else that you'll see here is whether the order is for research billing or non-research billing. So, every plan is going to have a research account attached and I’ll be able to see that in these order details. We'll kind of get into that a little bit later.

The next thing as a clinician, I’m going to want to choose which orders I order for my patient or not. So, I’m going to come over to these checkboxes. Now, there are three options for me as a clinician: there are the required ones which means I don't have to do anything as a clinician; it's going to come checked, I cannot uncheck it. It's something about the study protocol, the study has decided this is required for every patient no matter what. So, I don't have the option to uncheck it; I have to order it--but it's easy on me because it comes checked already.

The second option is that it comes checked but, as a clinician, I can decide whether my patient really needs that or not; maybe there's something going on with my patient and I don't want to give them this order, so I can uncheck the box if I desire; but it comes checked ready so I don't really have to think about that.

The final check box is going to be one that is unchecked. So, as the clinician, I have to decide if this study order is necessary or not. So, once I make those decisions, now that I’ve selected all the orders I want to place, I’d either go down to this bottom area and I’d sign it, or I can initiate now for orders that will need to be completed at another date or appointment.

So, when does a study use PowerPlans or orders like this? Well, it's going to be required for research billing; it basically facilitates the invoicing and direct billing for orders that will be sponsored. So, a sponsor is going to be paying for those orders; plans can have both sponsor-covered and non-sponsor-covered orders, but what the power plan does is it lets the system know that this is going to someone else to pay for and not the medical center, or patient, or someone else within the system. But even if it's not required for your study, there are some great benefits to PowerPlans. It streamlines order placement processes; orders are automatically associated with patients upon enrollment, I don't have to carry my protocol with me to determine, "Okay, Patient A is having this visit," "Patient B is having this visit," these are the orders, I need to go look it up. I don't have to do that; everything is within the EHR; it's already planned out for me and there's the details, and everything is filled out, I don't have to be looking at my protocol. It's all there right in the system for me. So, that's really great. Also, one plan includes all these visits as well, so I don't have to keep doing the same thing over and over.

So, everything--if you have a really long study--oncology studies, in particular--this is all very helpful. So, PowerPlans are quite useful in streamlining that ordering process.

Next, we'll go ahead and move on to PowerTrials. We will see our organizational diagram again; and PowerTrials is one of the research setting applications, and it has two primary sub-applications that we see here called Protocol Office Manager and Patient Protocol Manager. PowerTrials refers to the overall research package; that includes this pre-screening box over here; but the PowerTrials core is really Protocol Office Manager and Patient Protocol Manager. All studies that go into PowerTrials have this POM or PPM, but not all studies have pre-screening--and we'll get into that a little bit later.

So, PowerTrials overview. It is the Cerner research application and it, as well as its sub-applications, integrate into the EHR. It's mainly used for studying for tracking study protocols and patient enrollment, and it integrates within other sub-applications. So, pre-screening, which we will talk about later, and PowerPlans which we just went over. And then, finally, we are planning--the VA is acquisitioning a clinical research management system for the future; it doesn't currently have this, but we are hopefully going to get that in the next few years.

So, the tracking applications are going to be POM, which is also called Protocol Office Manager; another way to say it is POM, and this is where a study is going to track all of those protocols, milestones, study staff, and they're going to be able to maintain these documents here. And then PPM is going to be your Patient Protocol Manager which is you're tracking patient eligibility and managing study documents, and managing patient enrollments.

So, when does a study use PowerTrials? If you're using sub-apps such as pre-screening or PowerPlans, you're going to have to use the PowerTrials core. So, every study is going to have to have a protocol built into Protocol Office Manager; otherwise, it's optional and the great benefits of these is that everything can be input in one place; it integrates into the EHR directly, a study doesn't have to necessarily use Excel sheets and all these other kinds of documents to track enrollment, or look into the medical record, and then search for that name and last four of their digit; everything's in the system already. So, you can look at your patient list, click on a patient and voila, you're ready to do chart review, or consults, or orders, or look at your protocol; it's all within that same application.

So, the final sub-application for today is pre-screening. So, this is going to be that last sub-application that's not quite a part of the core, but is optional and it's about eligibility and recruitment. So, the overview of pre-screening is that it screens for this inclusion and exclusion criteria to create a list of potential participants; it does not replace manual chart reviews, but does narrow that patient list down. So, you're still going to have to go into the patient and make sure that they're fitting maybe other criteria that you weren't able to screen for, particularly because pre-screening only screens for discrete data elements such as age, sex, vitals, test results, BMI, anything that has kind of a numeric value or some sort of value to it; it's not going to be able to do any free text such as research notes or things like that. The great feature of pre-screening is that it's continually running; it is not static; it's constantly adding new patients and removes newly-ineligible patients. So, it's great for continuous review of eligibility.

So, this is a photo of the back-end tool. Study teams aren't going to be viewing this tool, we just wanted to provide you this example to show you really what happens behind the scenes with pre-screening and a little bit of the logic behind it. This is actually going to be built out by a new VA position called a research application analyst.

So, the first thing you'll see here is this sentence criterion; as we said, these are all our discrete data elements ranging from age, race, allergies, diagnosis codes, medications. And within each data element, there's going to be ways to search for specific criteria; that's going to be like a specific age, between an age, between a year between a month. So, like if I really wanted to find patients who were 75 years old, I could be able to say, "This person was born in such-and-such year," to receive patients who were only 75 years old--or above 75 years old. So, that's where I would just designate here. And these are done in if-then statements.

Something to note is that this process or this builder cannot screen for a clinic or a provider; however, in the front end, so actually within PPM and when you get your list back, that is where you'll be able to filter patients or potential participants by the clinic location; you just won't be able to do it here.

So, this is a pre-screening example rule. It's a list of--all of the criteria that I would have just created in that last photo is going to be put here; basically, we also have these extra specifications that we can do particularly with medications. So, if I wanted to see if someone was on this medication but I wanted to see if they were completed or discontinued, or in the future, I can definitely put that into the rule. You can also see that you can be active, or canceled, or inactive for certain diagnoses as well. So, there are a lot of things we can do with these rules to get more or less specific as needed. This is done in if-then statements; and then finally, those meeting all the criteria are going to be pulled into my pre-screening list for the study, then they'll qualify for my study.

Ashley Morris: So, this is an example of a pre-screening list, the list of patients. So, as an example, if I am a researcher and I’m going to do some recruitment for my study today, I would go into the PowerTrials application and I would pull up my study so I’d be looking at my studies information, if I want to refresh my memory see how many patients already have enrolled, what's my target for today, I could go and look at my list of currently-enrolled patients. But here, I’m looking to recruit more patients so I’ll be looking at my pre-screened patient list. So, within this pre-screened patient list, my list of patients, I’ll have the first and last name, and the medical record number or MRN; and so I’ll see that for all the patients pulled by the list. And so, the medical record number, that MRN, is the new number that will be used to identify patients in the Cerner system. So, rather than looking at patients by their name in the last four like we currently often do, we will use that MRN as the patient identifier.

Because of the integration between all of the different Cerner applications, while I’m looking at my list here, if I decide that I want to go and do a chart review and do some further eligibility screening on a specific patient, if I click on the patient's name, it will pull me directly into their chart. So, I won't be in a separate application and then have to pull up the medical record, and then search for the patient, I can just go straight into their record from here.

And as Mary mentioned, I can filter this list; I can filter by name, by status, by location, however I want to filter my patients; and I can also share these filters across my team. So, if I am screening these patients and I filter it by the clinic that we're looking for, I can share the filter so that everyone on my team, we're all looking at the same list because it's being filtered the same way.

So, we mentioned how the list is non-static and so it's constantly updating; and so, with that, the status of the patients in your list is crucial. So, here, a patient with the status of pending, that means that the prescreening tool has taken that list of eligibility criteria and pulled this patient as someone who might be eligible, but no one on the study team--I haven't reviewed their chart, I haven't spoken to the patient about the study, we haven't done anything. So, if this patient with a pending status suddenly goes on a medication that we can't have on our study, the tool will recognize that and it will pull them off the list because they are no longer eligible for my study. However, any other status, that won't happen.

So, the status of in follow-up; I’ve done a chart review, I see this patient might be eligible, I’ve talked to them on the phone once or twice, they're interested, we just haven't been able to get them into the medical center yet for inpatient, in-person visit so they're in follow-up. If this patient goes on that same medication, they're not going to be pulled off of the list because they have a different status now, they're in follow-up. So, there won't be instances where you've been playing phone tag with the patient, you've been tracking them; and suddenly, you go on your list one day and they're just gone, that won't happen. The only ones who will get pulled off the list are those who haven't been kind of touched by study staff.

Another piece to note is that there's not much PPI or PHI in this list; there's no health information; there's no social; there's no birthdays or addresses. To view any of that information, I would need to go into the patient's record; which means that if I do mass mailings or something like that or I need a bunch of--if I need that information for a large number of patients. So, for my recruitment, I do a mass mailing of 800 letters to veterans. I would have to do it solely through the pre-screening list here; I would need to manually go into each record and pull those addresses; and that does not sound like a fun time.

So, what I would do is PowerTrials data gets syndicated back to CDW; so this information, your enrolled patients, this list of pre-screened patients goes into CDW. So, I can use CDW to pull that list; and it will be through a DART application, so I’d put in a DART request with my study and say I want my list of pre-screen patients and addresses. And VINCI would pull out that list in the addresses and give that to me, and then I could use that to mail them. So, I’d have to use CDW; I couldn't get that information directly from this list.

And so, talking about CDW, if a study is not going into PowerTrials, how might they do recruitment? And the answer is actually pretty similar to the way that's done now, it would be CDW. And so, a very brief discussion of some data in future state, there will be three CDW databases. So, the first is kind of the current legacy CDW which is the VISTA that we are used to working with; the second database will be CDW Book 2 which is the Millennium data, so this is data coming from sites that have transitioned to Cerner; and then CDW Book 3 is the converged database, so that we'll have data from both VISTA and Millennium, so data from sites that have transitioned and have not transitioned.

And so, for a research study that's doing recruitment, you would put in a DART request and the VINCI data managers will provision out the data you need based on your project needs and data availability. So, as a study coordinator putting in a DART request, I don't need to know whether the data has to come first from CDW Book 2 or CDW Book 3 I don't have to kind of tease that out; DaVINCI data managers will be trained and they'll know where to go, so I just need to let them know what I need, and they'll pull it from me from wherever they need to go.

So, CDW will be a recruitment option for studies, pretty similar to how CDW is used as a recruitment method for studies now before the Cerner transition.

So, when does a study need pre-screening? So, pre-screening isn't required; no study needs to use pre-screening to find their list of patients, CDW exists; however, other ways exist, it's not the only way to do recruitment. But there are quite a few benefits. You can--very directly against the EHR--you can directly screen the EHR screening PowerTrials to constantly maintain that list of eligible patients. So, when a primary care physician completely unrelated to research puts this patient on a medication that makes them ineligible for the study because the applications are integrated, the pre-screening tool will realize that that has happened and pulled them off the list.

So, it's directly getting the most up-to-date information from the EHR, and also integrates recruitment and enrollment into one single application.

So, as I mentioned before, you can just click on a patient's name to go into their record for chart review; that won't be in an Excel doc, pull up the medical records, search for the patient; it's all in one application for ease.

One thing to note is that there is an alternate workflow needed if you are pulling large lists of patient data. So, in that example I gave about mass mailing, if you need any of that information, you will have to go through CDW to get that. But as I noted, PowerTrials gets moved into CDW and it's associated with the study name; so, it lives in CDW as one convenient chunk to find and to pull out, but it is a DART request process that you will need to do. So, we did want to mention that.

So, now that you've gotten a very quick introduction to pre-screening, we just have a poll of how interested you might be. So, if you're a researcher, on a Scale of 1 to 5, how interested are you in potentially using pre-screening for either current or future study? So, we have 1, which is, "Not interested at all," up to 5, "Which is very eager to use or very interested," and then we do an "NA, Not Application" option as well.

Coordinator: Alright. So, the answers are coming in quite rapidly. We'll just let that slow down for a few seconds before we close off everything. Again, please remember to submit your answers after selecting them for it to be recorded. So, it seems like things have slowed down quite a bit, so we'll just go ahead and close that and share the results. So, 0 percent said A; 1 percent said B; 5 percent said C: 10 percent said D; 15 percent said E; and 12 percent said F. And that's it.

Ashley Morris: Thanks. So, that's really interesting and glad to hear. Like we said, it's a very powerful tool and it can really help research with some recruitment. So, we are definitely glad to hear that some people are interested in using that as well.

Mary Schooler: So, now, we'll briefly introduce Data Collection Worksheets or DCWs; this will be our last topic of the session. So, Data Collection Worksheets are Excel worksheets that collect study information for PowerTrials builds. So, every study that wants to enter into PowerTrials or needs to, or is required to use any of the applications we've talked about today, we'll need to fill these out and give them either to a Cerner consultant or a research application analyst. So, this chart here just kind of goes over what function you'll need, and which DCW we'll need. So, studies requiring PowerPlans for research orders are going to have to have, at the very least, a protocol and power plan DCW. If people are using pre-screening to screen for eligibility, they'll need the protocol and pre-screening--and then if you just want to track your protocol or enroll patients without pre-screening functionality, you'll, at least, have to have a protocol DCW. If you want to use all three, you'll have to fill out all three.

So, before go-live, a Cerner consultant is going to do this for your site; there's going to be a whole process through that; and then after go-live, it's going to be done by a VA staff who is a research application analyst. And once these are built out in the system, the study team will be walked through their build and verify accuracy; and then once all their IRB applications, and sponsor applications, and things are approved and they're ready to go, they'll be able to start using the system. The research application analyst, by the way, is going to be a new position that we are currently creating SOPs and workflows for.

Ashley Morris: Alright. So, that's it for our overview of PowerTrials, the Cerner research application. It looks like we've got seven minutes left before the top of the hour, but we will be glad to start answering any of the questions you all may have.

Coordinator: Great. And we have several questions that have come in. Starting with, "Will PowerChart work like CPRS, and that you can only enter notes or orders for veterans at your home site?"

Maria Souden: Thanks, Amanda. Hi. This is Maria. I could probably take that question. So, we are working through some of the access processes and the role assignments, but actually, once we're in the Cerner EHR, we are all on the same system, so it's one of the great benefits of the national--it's a truly a national EHR instance; and so, you will be able to access the EHR and the patient record for anything that has been associated with your name. So, if you're on a study with patients at multiple locations, you'll have access privileges at those locations as well.

Coordinator: Great. And will PowerChart clinical trials also be used for observational studies?

Maria Souden: I could probably take that one too--sorry, go ahead.

Ashley Morris: This is Ashley. I was just going to say that PowerTrials is mainly intended for clinical trials; some of the functionality is best-suited for clinical trials. But there are features that can be helpful for observational trials; there are a couple observational trials that are considering or using pre-screening or cohort selection, so they could use the application; not all the features might be relevant, but there are features that could be useful and could help those types of studies.

Coordinator: Great. "Will or can power plan orders be sorted by each study?"

Maria Souden: Yeah, you probably can answer this better than I can, Ashley. But I think the question is like when you go to look for your PowerPlans, are they grouped by study? And I believe they are in the hierarchy.

Ashley Morris: Yeah. So, each study will create their own power plan, so it would have their power plan name and then all the orders that the study has said that they need. So, it would be by study and so it would be--you could see "RES study name" and like, "Oh, this is the research power plan." So, it is by study--I hope that answers the question.

Coordinator: And, "Are the pre-eligibility queries able to be built by the investigator or is it built by Cerner and do we have to document HIPAA waiver first?"

Ashley Morris: So, there will be guidance, obviously, about all of this, but you will have to have all of the approvals before you can see this list. So, your R&D approval, your IRB approval, so you will have to be sorted on the approval side. And then there was another piece of the question which I have, unfortunately, forgotten.

Coordinator: I think it was about the building of the power plant or the pre-screening.

Ashley Morris: Right. So, the pre-screening building is the--the city team in the DCW, there's an Excel form that gets filled out about what inclusion and exclusion criteria there is, and so that will get built concurrently while the study is receiving those IRB and R&D approvals; and then once the approvals--and so that building piece before go-live will be done by Cerner teams; after go-live, it will be these new research application analyst positions. So, it depends on when it's being built up to whether it's Cerner or VA, but it will be built while the study is receiving IRB or R&D approvals; and the study will be given access to that list and that list will be run once all the approvals have gone through.

So, within the system, so within the pre-screening system, there won't be a need to like upload a HIPAA waiver, but you will have to--if your study is getting a HIPAA waiver, your IRB approval for all that, you will need to have that IRB approval before you can use that list and get that pre-screening list.

Coordinator: And how does blinding to treatment condition work when placing orders?

Ashley Morris: So, with the blinding and the orders, there are a couple of different ways to do it which get a little pretty detail-oriented; but basically, there are ways to either make things general or some different ways that studies that are blinded will be structured in PowerTrials so that the orders can remain blinded. To go into any more detail, it would be pretty long, but that's the short of it.

Coordinator: And one last question, what is the specific clinical research management system that the VA is acquiring?

Mary Schooler: So, that has not yet been determined yet, so the acquisition process is going on right now.

Coordinator: Great. And do the presenters have any closing remarks they would like to add?

Maria Souden: This is Maria. I just want to thank Ashley and Mary for the presentation, I think that will be really useful to people and I want to thank everyone for coming. Thanks.

Coordinator: Yes, thank you so much to our presenters for taking their time to present today's session. And to the audience, if you have any other questions for the presenters, you can contact them directly; and please tune in for our next Research & EHR Synergy session which is Lessons Learned from Non-VA Health Systems about EHR Modernization on April 28th at 12 PM Eastern.

Thank you once again for attending; we will be posting the evaluation shortly. Please take a minute to answer those questions; let us know if there are any data topics you're interested in and we'll do our best to include those in future sessions.

Thank you. And have a wonderful day.