Angela Foster: Welcome, everyone, the agenda for today, we'll have some brief announcements. Then we'll go through a few introductory slides to give you some background on how we develop the dashboards, and what they contain. And then we'll move into the dashboard demonstration. The next slide, please.

Just a few announcements regarding the VAIRRS program. One, the updated project cover sheet wizard is available in the sandbox, and the outline is posted in the VAIRRS SharePoint site. So please, if you have not already reviewed the outline or the draft in the sandbox, take a look, and send us your feedback.

If we, our plan is to publish the final version in production by the end of this week, but really want to make sure that everyone gets a chance to review those changes.

Secondly is the Strategic Advisory Council. We are putting together the VSAC for the VAIRRS program, and we are encouraging anyone who wants to participate to submit a nomination. You can nominate yourself, if you desire. We will be reviewing those nominations next week, and hope to start the VSAC meetings in early May.

Finally, the RCO and COI workspaces are in development. We completed the contract modification that needed to be done in order to incorporate those workspaces. And over the summer, we're going to be speaking to those communities, the RCO community as well as the COI administrators, and configuring those workspaces, and so forth. So stay tuned for more information on the RCO and COI workspaces.

Thank you, the next slide, please. Alright so now, I'll turn it over to Katrina Young. She's our Manager for the Support Team, and she's going to walk you through some few slides before handing it over to Nelson Vasconcelos, who is our Dashboard Developer. Thank you, over to you, Katrina.

Katrina Young: Well, thank you, Angie, and welcome, everyone. So just as Angie said, I will go through some brief slides before we actually get into the dashboard demonstration. Okay so first, to give you some, a little bit of a background story on how the field staff dashboard was developed.

In summer of 2019, VAIRRS rolled out the dashboard focus groups to provide site level feedback regarding the use of IRBNet. The results and all the feedback collected from those focus groups provided insight into the demands of IRBNet users, and ultimately led to the development of the field staff dashboard.

So as you can see below, we pulled feedback from a number of various roles within the VA research community, including associate chiefs of staff, admin officers, down to research compliance officers, and all members, and coordinators. So it was a shared effort across the board to roll out this dashboard.

So some of the key features and pages that you will see when you get access to the field dash – staff dashboard, so one of those pages will be the active project detail page. On this page, you'll be able to reference qualitative data around your active projects at your facility. So that includes PI name, title, and risk level of projects, funding codes.

And something that's really cool, is that you'll be able to filter by tags within IRBNet. Another page that you'll be able to access is the human subjects research page. The, all of that page brings up data points regarding human subject research, so you'll be able to reference drug or device information for active projects, as well as informed consent, down to a list of protocols, and compliances per your projects.

And one of the the, the actual pages that's super important, and one of the first pages that you'll see is the active projects overview page within the field staff dashboard. That page references a lot of your total qualitative data around, within IRBNet, referencing the total number of active projects, including the total number of active projects by risk level, by submission type, and so on. And yes, Angie, please jump in.

Angela Foster: Thanks, Katrina, I apologize for interrupting you, but I did want to mention, there's, there's one important distinction that we need to make. And I really should, yeah, I want to make sure it's clear before the demonstration starts, and that is that the projects that are reported on the dashboard are your locally reviewed projects.

I understand, it's really important for you to have access to the Central IRB project details, however, we're still working on the best way to relay the Central IRB project back to the local workspaces. So until we get that done, we thought it best to just not include Central IRB projects in the field level dashboards to prevent any confusion, or to prevent projects from being reported into workspace.

Thank you, that's all I wanted to add, to include, Katrina.

Katrina Young: No a great point, thank you for adding that in. And just another page, just some additional pages for you all to be, that you all will be able to reference in that field staff dashboard, as well as your project coverage sheet completion page, personnel, project personnel, animal research, safety research, closed project detail, a data dictionary, as well as a single project detail page within this field staff dashboard.

Angie already said that this is, this will be all pulling from locally reviewed projects. And just something else to note before we actually get into the demo, and I give our instructions on how you can access, is that a lot of information within these pages are pulled from the project cover sheet wizard.

So it's super important for your facility to complete the project cover sheet wizard for all of your active projects, and make sure that the information in those wizards are current so that it can reflect correctly, and that the field staff dashboard is, can be made of best use, and optimum use for your facility.

Okay so getting in, how to access the dashboard. So within the VAIRRS SharePoint we created a tab that's called VAIRRS field staff dashboard. So once you click that tab, you go to the the VAIRRS SharePoint site, and you can click the tab that says, "VAIRRS field staff dashboard," it's usually right below the – right above the site recycle bin.

On that page once you click that tab, there will be a short form where we ask for your name, VA Medical Center location, as well as your VA e-mail. Once you click, 'submit,' the VAIRRS support team will receive your request, and we will grant you access to the field staff dashboard. And if there are any other questions or if you have any issues, follow-up with us via e-mail at VAIRRS dashboards at VA dot gov.

Okay with that being said, I want to turn it over to Nelson to walk through the dashboard. So Nelson, take it away.

Nelson Vasconcelos: Thanks, Katrina. Am I able to share my screen, Parker?

Parker Cunneen: I'm gonna set you as presenter, and it should be going through any second.

Nelson Vasconcelos: Perfect, thanks so much. Alright, hopefully, you should all be able to see the screen now. Thanks so much for for taking the time, and and good afternoon. So I'll just provide a quick, sort of, run through of the VAIRRS field dashboard, and, sort of, to to follow up on on what Angie, and Katrina pointed out, sort of, the benefits, and and how it can, sort of, improve your work.

So we start here with this welcome page. Just a quick note, some of our our focus group users had issues viewing this in Microsoft Edge so we recommend that you use Google Chrome, if possible. It's working for me in Microsoft Edge, but some folks have a few issues with that.

But the welcome page has, sort of, high level information about the projects at your site. So for the purposes of the, this demonstration, we'll be looking at Miami, but you will have, you will see the information for your site. So that's why it's important to, when you're requesting access to indicate your VA facility, so that we know how to, sort of, assign those permissions so that you're only seeing the information that's relevant to you.

And just to provide a little bit of info that Katrina, sort of, already provided; who we worked with, and and in the importance of the project cover sheets. The more comprehensive information becomes available, the more of the cover sheets that are completed.

And then at the bottom here, we have a feedback form, and you would just click on that. And it will just open up, just a quick form. It doesn't seem to wan to open at the moment. But once you have access and you take some time around the dashboard, if you can take a few minutes to provide your feedback, so that we could always continue to work to improve it.

And then there's a button here for the project cover sheet completion page. So this actually shows of your active project, how many have cover sheets completed. And then you also have, sort of, a percentage there. Now, you can use filters here. So if you want to see, okay, which of our cover sheets do we need to complete?

Now, we filtered down to just these 39 projects that need a project cover sheet completed, so that it's a little bit easier to, sort of, access that. I I will also add that we will be adding a similar page to this for the IRB information sheet. And that will be coming in the, in probably, in the next few days.

Next, we have active projects overview, so it just provides a little bit more context to your active projects, sort of, how they're constituted, and things like that. So we have charts for projects by risk level; just to note here, that right now, for example, we have 48% with either 'other,' or, 'none reported.'

So because of, because not all of the the cover sheets have been completed, the risk level, if if there's no risk level indicated, it doesn't necessarily mean there's no risk. It might just mean that it hasn't been reported to help folks get project by board type and funding bin.

And then we have drop down filters here; for example, if you wanted to just look at new projects. For example, it's dynamic, and you can, sort of, see the numbers change there; and then the similar, sort of, funding bin, board type, et cetera. And then to go back to the original, you can always just choose, 'clear filters,' and that will clear all of the filters for you.

Next, we'll look at the active project detail page. I think this page has a lot of rich information, so we'll take a little bit of time to, sort of, go through it. This provide a whole host of information about the active projects at your site.

So you can see the keywords that were indicated with submission type, how its funded, risk levels, et cetera, the current status. This table, sort of, has a lot of, sort of, information, and some folks prefer to, sort of, look at it in a more tabular view in Excel. So there's a way to do that.

Over here, you'll see the little dots on the right with more options, and you can choose to export the data. You click, 'export data,' and you can just choose data with current layout. I'm not going to export it now because it takes a minute or two so I'll just show you the the product I exported a little bit ago. And now it's an Excel and you can, sort of, manipulate, and filter however you'd like, if you'd prefer to look at the data that way.

Additionally, as Katrina pointed out, there's a a keyword, there's a a search filter so you can search by keyword, tag, the IRBNet ID, project ID, the name of the primary investigator on that project, or any words in the project summary.

So I'll show you, sort of, a couple of them now. So if you wanted to look at, and we'll just look at that first PI named Holt, and if you just wanted to look at their projects, they'll just take a second. And there you go, so now you, it filters down to the PI.

And then over here to the right of the search box, you'll see a little eraser. You just click that and that will take you back to the default. And then similarly, say you wanted to look at COVID projects, you just type in 'COVID,' and then anything that pulled from either the project's summary, or the keyword, or the tag will show up.

And so you see here, these are in the keywords. And then in some cases, they might be in the tag. And then in some cases, it might be in the project summary. And again, you just click the little eraser to get back to your default.

You have these filters up here, they just drop down. You can see through which department it was funded, by risk levels, the board that it was – that is reviewing it, the current status, and whether there are contracts or agreements.

Additionally, Katrina mentioned the single project detail page. So you can look for additional detail and there are actually two different tables I can show you. If you right click on the project ID, it brings up this menu. And then you see here where it says, 'drill through,' that will take you to two additional projects, two additional pages. Excuse me.

I'll show you the single project detail page. You just click on that, and that will provide additional, sort of, context and detail on that particular project. So you see the tags here: COVID-19, \_\_\_\_\_ [00:17:01] ID, et cetera. Here's the full project summary, ID, the PI name, keywords, all this, sort of, information for one project.

You have a little arrow up here, and you can just click that, and it will take you back to this page. And now, so I'll also show you the second drill through page. It's called project personnel. So again, you would just, I'll show you again.

You just right click on 'Project ID,' you go down to, 'drill through,' choose 'project personnel.' And now, it shows you, again, the the high level info, the project ID, title, and PI name. But if you need information, if you need to contact a study coordinator, for example, you have that information with their name, and VA e-mail, and their role on the project.

And then again, you have this arrow here, and you just click on that. And that takes you back to the previous page in the report.

The next few pages are, sort of, scaled down versions of the active project detail. This is the the human subjects research page, and as we would have expected, it's just projects involving human subjects.

And we have a few different filters here, repository information, data repositories, et cetera. If they involved special populations, again, the risk level; if they are investigational drug studies, or use medical devices.

And then it also has counts for each of those categories as well. And then similarly, of course you can, you can export the data into an Excel table. You can do the search by keyword, PI names, et cetera, so it works very similarly to the active project detail page.

Then again, we have the animal research page. Obviously, some of those filters aren't really germane for the animal research page with this population, they're drugs, or what have you. But it provides a tabular look at all your animal projects, so this might be useful.

Again, you can still search and then you could export the data, again. And then looking at the safety research, same sort of thing is at play here; the search function, and the export data function.

Next, we have the review process, and now, this is looking at all the committee reviews, sort of, taking place. Severally again, you can look at, if you want to look at just the exempt projects. You can filter that way, again, similarly, project risk level or type, submission types.

And then I should also point out these, these filters here with the sliders. So if you wanted to look at, or we actually have a project expiration page, and I'll show you that in just a moment. But if you wanted to look at the agenda dates, so if you wanted to look at just projects from this year, you can either type it in, or you can use a little calendar function.

But let's just look at agenda dates of '20…. I'm sorry about that. That's what I was looking for. I think my number lock, the function isn't working quite right. But if you wanted to look at agenda dates for just 2022, you can do that.

So now, these are just those of the2022, but you should be able to also just type in the calendar date as well. And again, you have the little eraser here to clear it and go back to the default.

Next, we have the project expiration approach I was just referring to. I'm going to switch the view just to show, there's only one project that's close to expiring. So I'm just going to push to Albuquerque real quick. We'll see these projects, and again, it's a lot of the the similar information, but if you scroll here to the right; and again, this might be one where exporting to Excel is helpful.

It will show the days to expiration. So this report contains any projects that are within 30 days of expiring or have expired. And you'll see, the ones that have expired here in red: This expired 77 days ago, 50 days ago, and then in green are the ones that have not yet expired but are close to expiring.

You see this one expires on the eighth, so there are 12 days left to expiration. And then again, you can always use the search box, the date sliders, or the drop down filters. I'll just switch back to Miami real quick.

And now, these are basically just a tabular look at all of the closed projects, whether they are closed, withdrawn, disapproved, et cetera. And again, this might be one where exporting that to Excel is a useful function for you. So that more or less covers it; I'll also show you the data dictionary.

So this just, sort of, details the different data sources that were being, that were being used from VAIRRS. So we have that project cover sheet, the IRB info sheet, active projects, the global tags report. And then descriptions of a lot of the data, data columns that you'll see in report, it will show you which page it's on, a brief description of what that data represents. And then the source from VAIRRS of which project, or which report or report are used to, sort of, determine that.

So that more or less covers it. Again, I encourage you to provide some feedback, so we're always looking to improve your experience. And again, looking at, I I, I think the more you use the reporting, you'll see that project cover sheet completion really help enrich that data.

So I also encourage you to to check out the the project cover sheet completion page, take a look at which project needs cover sheets completed, and go from there. Thanks so much, I will hand it back over to Angie.

Angela Foster: Thank you, Nelson, and that was a great walkthrough. And so now, I believe Parker has an announcement, and then we can move over to the Q&A.

Parker Cunneen: Yeah, thank you, Angie. I just wanted to let everyone know, we we had some technical difficulties in the beginning, but but got our live close captioner with us. So I'm just posting a link in the chat for everyone, and if anyone needs closed captioning, they can use this link to view it. Thank you.

Angela Foster: Thanks, Parker, so we can get started now with our Q&A. I did, I did respond to a few questions in the Q&A chatbox. But just to make sure that everyone sees those responses, we can just go through those really quick.

The first was about IRBNet training. So we do have a number of training resources to include the training, recorded webinars, training energizers. All of these training resources can be found on the VAIRRS SharePoint site.

The next question is regarding tags. So are are tags included as one of the data sources? Yes we do include the \_\_\_\_\_ [00:24:39 to 00:24:43] tags of \_\_\_\_\_ [00:24:45 to 00:24:48] global tag report for \_\_\_\_\_ [00:24:50 to 00:24:51].

Parker Cunneen: Angie –

Unidentified Female: \_\_\_\_\_ [00:24:54].

Parker Cunneen: – We, I think we lost the audio there. If you might want to repeat that answer?

Angela Foster: Sure so so –

Parker Cunneen: Yes.

Angela Foster: – For the tags, I was just saying, we are using the global tags report. And we, you can also get that report delivered to you for your site if you would like to receive the the global tags report for your workspaces.

The next question is, "After submitting a request for access, will we receive an e-mail when that access is granted?" Nelson or Katrina, do you want to elaborate on the request process?

Nelson Vasconcelos: Sure, yeah so and thanks for your question. Or yes you you do receive an e-mail. Once we grant access part of that process is automatically generating an e-mail to you to let you know that access has been granted. And it will provide you with a link to the dashboard.

Angela Foster: Thanks, Nelson. Alright, the next question. For the drill through project personnel, does that get updated as staff amendments are submitted, or does the project cover sheet need to be updated with all amendments for this dashboard to work?

The project cover sheet, it should already be \_\_\_\_\_ [00:26:17] updated if if the study team is submitting an amendment, especially to change the study personnel. But the only way that that change would be reflected on the dashboard is if a revised project cover sheet was submitted. We captured the latest project cover sheet data, and that's what's reported on the dashboard.

The next question? I think that was the last question submitted in the Q&A box. So if you have more questions, please fire away. And we'll give everyone a few minutes. I'm sure, everyone is typing in your question at the same time so we'll give you a few minutes to get those into the Q&A box.

While we're waiting for for more questions, just to reiterate; Nelson displayed the data dictionary page. But I would like to encourage you, if you have questions about your data, why is something reporting a certain way on the dashboard?

Review the data dictionary, it gives you a lot of information about where we're getting the data from, how that data is being reported on the dashboard. And it it may answer that, your question about why a certain data study is being reported as such?

Okay, next question, should studies be submitting the revised project cover sheet with every amendment revision? Only if that amendment is related to items that were previously reported on the project cover sheet.

So if if, for instance, change in study personnel, if that amendment changes the personnel that were originally reported on the cover sheet, then yes, the cover, revised cover sheet should be submitted so that the details that we're collecting in that cover sheet are consistent with what's currently going on with the study.

The next question, please. Can you please put a link to the dashboard on their SharePoint site if there isn't one – not seeing it? So we can't link to the, to the dashboards because everyone's access is determined based on where you're located.

So and, Nelson, correct me if I'm wrong, but one general link to the dashboard would not work based on the role level security that we have to attach to each user.

Nelson Vasconcelos: Well, not necessarily, I mean, there's one link for everyone. And then so the role of security is determined once you get in there, but you do have to have access to the dashboard. So if if you don't yet have access, you will be able to see it.

We, as there will be no harm in adding the link to the dashboard but I think my my only question is, would, would some people not understand when to pass along, and things like that? As I pointed out in in the earlier question, you will receive a link to the dashboard once you have access.

So I would recommend, once you get access, you'll have a link to that dashboard, and then you can just bookmark it on your browser to view whenever you need to.

Angela Foster: Thank you, Nelson.

Katrina Young: One thing to add, and just if they could clarify this question just to make sure they're not referring to the the request link? And if this is, like, if they want to link to the dashboard itself, it's not there. But if you're referring to the field dashboard request form that is on the SharePoint, let us know if you're having any issues, and if you're you're not able to see it.

Angela Foster: Well, thanks, Katrina, the next question, please. Our site has a multi-site IRB, should I, should I be able, should I have access to the studies reviewed for other sites? No you should only have access to the studies reviewed at your site.

Okay, on active projects overview, the risk level is only pertinent to human research, not all studies. Pie graph is misleading as to completeness of this information for all human projects.

Okay, so thank you for that feedback. I, if it's not too much trouble, I'd ask that you provide this feedback using the link on the dashboard to make sure we capture it, and and can act on it. The dashboard team can act on it. But thank you for that feedback.

Do project cover sheets need to be submitted for QI projects and or previously closed studies? No we don't need it for the closed studies. We do need it if the QI project is being reviewed locally. We would ask that a cover sheet be submitted for that project, we can capture if they're coming in for determination requests.

Is the access request live now? Is the system slow because there are multiple requests now? I am unable to request access. So it should be live. If you're running into an issue, it may be that there are so many people requesting access. I would say give it a few minutes.

If you still cannot get it to work after the next 30 minutes or so, shoot us an e-mail at the VAIRRS dashboard's e-mail account, and we'll look into the issue. If a person on the study just needs to update, change their last name can that be done on the project cover sheet, or would an amendment need to be submitted also?

So I'm going to be very careful in how I respond to this because I don't want to touch the regulatory requirement. I will say that aside from whatever is required to be compliant, you can include a change name on the project cover sheet.

The last question, the last question in this, would an amendment need to be submitted? I'm not going to address that portion, that is up to the regulation in whether or not a formal amendment needs to be submitted for a, to change a person's last name.

No I'm not saying they must go through IRBNet, it depends on the site. Some sites put their QI projects in, some sites don't. I'm just saying if the, if your site is entering QI projects in IRBNet, then they should be accompanied with a project cover sheet with it. But it's all dependent on your local, local SOPs and how you review QI projects.

Okay, is the QA, QI determination live yet? I'm not sure what's meant by, "Live yet," QI, QA determination. If you can expand, whoever submitted this original question, Randy, thank you, if you could expand on that a little bit? I'm not sure what you mean by, "Is it, is it live yet?" Can you use VAEDA? So if you'd like to use VAEDA, you certainly can. We are still in the soft launch phase.

We plan to go into full launch at the end of the summer, but there is no restriction on sites that are using VAEDA during the soft launch. So Randy if your site is not already included in the soft launch, shoot me an e-mail, and I'd be happy to send you the link for VAEDA.

And for those that don't know, VAEDA is the VA Electronic Determination Aid. It is a decision support tool that allows the end user to go through a series of questions, and based on their responses to that question, to those questions, it generates a determination. So it's very useful, we've gotten very good feedback on it.

Like I said, it is in soft launch. We have about 17 sites participating. If you'd like to take a look at it, you can e-mail me, and I'd be happy to to get you started on VAEDA.

The next question, please. Okay, on the review process page, what exactly is displayed? Is it the last action on a study? So the review process page pulls in actions from all of your individual workspaces at your site. And the difference between the review process and the active, the other data that we're presenting, the active project human animal safety, is that the review process page does not restrict based on the project status.

So even items that are, or projects, or packages that are just acknowledged, or in some cases if it's disapproved, all of those will appear on the review process page. And it's the same data that is contained in your site's review process insight report. So again, if you don't already receive that report, you can certainly request it from IRBNet report.

Next question, please. Will parts of the facility director's report be removed from the report as the information would be collected from the dashboard? So no, the the field dashboards have no crossover to the facility director's report. I would say that if the original requester, Kristen Gephardt; I'm not sure if you're in RCO or not?

But if you are an RCO, we do have plans to include certain metrics that are reported in the facility director's report in the new RCO workspace. So stay tuned for more information on that. However, to repeat, the dashboards that we're presenting now have no relation, or do not crossover to the requirements for the facility director's report.

Okay, about the review process page again, okay, does it only show the most recent event for a particular study or does it show all of the review process actions for each of the packages for one particular study? I believe and and, Nelson, correct me if I'm wrong; I believe that the review process report pulls in the latest action.

It doesn't pull in a complete history of a project for every package that has been reviewed within the project. I believe it's only the latest action that's been reviewed.

Nelson Vasconcelos: Sorry, I was muted. Yes that's correct.

Angela Foster: Thank you, alright, the next question. I think that, that was our last question, so we'll give you all a few minutes to to enter more questions into the the chatbox.

And again, just to reiterate, the data source for all of the pages in the dashboard are the IRBNet Insight Reports. If you do not already receive Insight Reports for your site, you can request those reports to, by e-mailing IRBNet at govsupport at irbnet dot org. There's also an Insight Reporting guide that speaks to each of the reports that are available and what those reports contain.

So we will continue to wait for questions. We'll give it another few minutes, we have until the top of the hour. No so if there's, there anything else that we should go over? I know the the walkthrough was really comprehensive, any other tidbits for the, for the end users to help them navigate the dashboards?

Nelson Vasconcelos: I I would just put this, we do have a quick question, but before we get to that, I I will suggest, sort of, reiterate; take your time, sort of, explore if you see something you have additional questions on, please use that feedback form that we, we're trying to constantly, sort of, improve that. So I just want to encourage you to do that but we do have a couple of questions if you want to take a look at those.

Angela Foster: Okay, let's see. Is it a local decision if the project cover sheet is updated with any applicable information, or is this a VAIRRS requirement? This is a VAIRRS requirement. The only way we can accurately report on the data within VAIRRS is if that data is kept current and updated.

When will we get dashboard data based on the IRB information sheets data? So that's a great question. We are adding the IRB information sheet completion rate, that's our first update based on the IRB information sheet. And we're working on that update now.

As we get through the iterations and get feedback from you all, we can determine what else needs to be added to the dashboards. But right now, for instance, on the human subjects page, the data specimens, the special populations, all that's coming from the IRB information sheet.

Okay, \_\_\_\_\_ [00:43:39] have any questions? Where is the data regarding consent types and HIPAA types on the human subjects research page coming from? So that is coming from the IRB information sheet.

The next question, I'll go ahead and read it. Is there any restrictions on who will or will not get access to the dashboards? No, the only restriction is that you can only get access to the dashboard at your site. But as far as the roles and who can request access, they're not restricting access on, based on role, only providing access to the data from your site.

Alright, we'll give it a few more minutes for any additional questions before we close out. Again, we encourage your feedback. This is our first initiative where we are publishing dashboards for the field. So there, anything unexpected, any unexpected behavior, any unexpected results in your data, we would love to hear from you so that we can address those issues.

And also for you locally, take advantage of these dashboards to help you ensure the data that's being inputted into IRBNet is as expected. We hope that the dashboards will help unveil any inconsistencies with how you're tracking data locally.

Alright, if there are no final questions, Parker, I'm going to turn it back over to you to close this out.

Parker Cunneen: Well, thank you to the panelists, and thank you, Nelson. I know, you're not a regular attendee here, so thank you for joining us, and doing that demonstration. Thank you to the participants for joining us. As I mentioned in the beginning, we do appreciate if you fill out the survey.

And also the, as I said in the beginning, the webinar will be recorded. So feel free to reference that in the future. With that, I'm gonna just say thank you and close it out.

Angela Foster: Thanks, everyone.

[END OF TAPE]