[Job 5900441]
2023 BAA Day
October 25, 2023

CONFIDENTIAL ROUGHLY EDITED REALTIME FILE
Compliments of Birnbaum Interpreting Services

****

This file was created in real time by a Realtime Captioner. Communication Access Realtime Translation (CART) is provided in order to facilitate communication accessibility and may not be a totally verbatim record of the proceedings. A consumer should check with the presenter for any clarification of the presentation.

****

>> Next slide, please. Here's a few links I just at added in as part of the event page. We have the FY24BAA announcement already published. Thank you to our new program leader, Dr. Chada, this was posted, I believe, October 22nd. You can click through the link to get to the announcement which includes the priority areas for FY24 solicitation. The next link refers to the BAA agenda as I mentioned. It's a very busy day for us that we have planned. The initial portion of talk will be from the centers and offices where they do want to present their research priority areas of interest for research, for FY24 solicitation and the later part of the agenda includes the programmatic process and announcement updates by Dr. Chada and our contract program lead and Jessica will also be accompanying them for the Q & A panel at the end of the day. So with that said, I'm going to hand it over to Vidya, are you on?

>> Vidya: Yes, I am, thank you. Good afternoon! Thank you very much. Good afternoon, everyone. Thank you very much for joining us again at BAA. I'm Vidya Vish at an acquisition and grant services. Currently I have three branches in my division. I'm one of them is the scientific support branch which is in charge of hosting BAA solicitation, awarding and administering BAA actions. As she mentioned, we posted this solicitation for the FY awards in October 22nd in Sam.gov. The program offices, the centers, which participate in the BAA program between FDA, center for biological and evaluation research, CBER, center for drug evaluation and research CDER, center for devices and radiological, CDRH, center for food safety and applied mutations, center for tobacco products, CGB, veterinarian medicine, CVR, national center for toxicology research, NCTR, office of digital transportation, office of ORA and office of the commissioner and operations, OC and OR role.

I believe the BAA mechanician is an innovative, contracting process that allows academic institutions to present their ideas can and proposals to the scientific thought and leaders for consideration. For public health as the government may not address this. Be advised that the field of the BAA program will elaborate on it further, later on at 3 o'clock this afternoon. Thank you again for this opportunity. I'm going to turn it over to Dr. Chada.

>> Dr. Chada: Thank you! So please start the poll, Gretchen.

>> So on your screen, you see a poll for two questions. One is a yes or

nowhere we're requesting to see if you're aware that FY24BAA applications are required to submit a free standing paper and free standing proposal and the second polling question is, any topics of interest that you would like to be covered in the presentations or Q & A sessions. Please let us know. I would like to request the AV team to share the results of the poll. So it looks like we have some difficulties sharing the results. The events will be shared later on in the page. So with that, we will get started with the first presentation on the session of funding priorities.

>> Hello, my name is Sam and I'm in the office of generic drugs, office of research and standards. We orchestrate the GDFUA science and research program. With our discussions with stakeholders, there's eight areas we have identified that were scientific knowledge gaps greatly impacting the development of generic products, the development and assessment of FDA. So this is a priority for us to advance research in these areas so we can build the scientific bridges across the knowledge gaps and thereby, create efficient, scientific and regulatory pathways that enhance patient access to high quality, safe, effective and affordable generic drug products. So in the next coming slides, I'm going to highlight the priorities for FY2024. I will mention here, this presentation reflects my view and should not be construed to represent FDA's views or policies.

So the first research area relates to nitrosamines. Here, the priority is to evaluate potential risks of harmful impurities such as nitro SA mean and this includes using modeling and simulation approaches to assess the risk of altering the performance of generic products in the event of a reformulation. Also, for developing analytical methods and approaches to use orthogonal methods for the identification and quantification of know TROE sating species, in an ingredient or drug product.

Moving forward, really some more research on the nitrosamine area is related to the different functional groups in API, like tertiary amines, beyond secondary amines and other factors that can improve our ability to predict the formation of the nitrosamine NSDRI or small molecule nitrosamine and the risk of the formation under relevant conditions for pharmaceuticals and finally, the fourth sub area for the priority under nitrosamine relates to estimating accessible intake amounts for impurities using certain mutagenesis, invitro, in silico and these QSURs models. The priority of research is NOL analytical methods as well as improving and standardizing existing methods to characterize the components including impurities that can support a demonstration of the sameness for all of the nucleotide API as well as standardizing the in vitro methods for assessing the immunogenicity including their associated impurities.

Next will relate to complex dosage forms and formulations and trying to develop and enhance the efficiency of bioequivalence approaches, BE approaches for the complex forms and formulations. Here, it's about elucidating drug release methods for long acting, R in correctable, insertable or implantable, LAI products with the goal of predicting envy VOE to support this.

The next area of priority for research relates to complex routes of delivery. Here, research we hope to focus on implementing characterization based in vitro methods with in vivo PK and modeling methods as alternative to clinical endpoint BE studies typically for nasal and inhaled drug products but also, developing efficient BE methods for topical drug products, applied to the skin or other areas of local action that

may contain compositional differences, for the perspective generics relative to the relative standard and related to this is the research that is needed to improve IVPT and in vivo cutaneous PK-based study designs and beta analysis that help resolve practical changes with implementing these methods so that we can use them to support the demonstration of BE for topical drug products.

Next relates to complex drug device combination products so here the research priorities involve improving data analysis approaches for assessing comparative task analysis and comparative use human factor studies as well as developing improved criteria that is supporting the demonstration, such as transferable delivery systems or metric evaluation of device design changes for incorrectable and inhaled drug products, the point being to eliminate the need for certain in vivo studies and the other research area relates to developing efficient approaches to support transitions by generic products to utilize more environmentally friendly propellants.

Oral and parental generic products are research priority particularly for those that help to utilize oral physiologically based PK, modeling to identify risk factors for food effects, formulation dependent drugs interaction, to support global harmonization for BE for these products. We're also interested in research that can HEL elucidate how ingredients can modify drug release in these products, how they function to facilitate the implementation of risk based approaches to support biowaivers for these modified release products can and to elucidate BE for special patients like pediatric and perhaps, geriatric populations and others.

Moving forward with another area under oral and parental relates to developing evidence to support the feasibility of this for parental and ophthalmic, that have differences and to support the global harmonization of the most BE approaches for these products as well. The next relates to modeling and simulation and the integration of modeling evidence with empirical evidence. Model integrated evidence MIE to support the demonstrations of bioequivalence. Here, we have prioritized research for advancing MIE to support the efficient demonstration of BE specifically to locally acting products. These are for example, inhalation and topical routes of delivery as well as for the LAI products I have mentioned before. And also, research that helps to establish best practices for model standardization, validation, acceptance and sharing and you can hear an example here, using model master files that improve the reusability and re predictability that is used in BE study simulation.

And the final and 8th research area that a priority relates to artificial intelligence and machine learning as AI and ML tools. Here, we're looking for research that can help us to improve the use of real world evidence for post market surveillance of generic drug substitution and evaluating the impact on public health and research integrating ML tools with FDA information and data to support quantitative analysis and modeling approaches that facilitate a regulatory assessment and identify strategies to optimize reliability of the outcomes produced by these tools and be final, exploring the this for the tools, for the perspective applicant to look at the abbreviated new drug application, ANDA to enhance the efficiency, consistency and quality of regulatory assessments once these ANDAs are submitted.

So I will close by saying there's more information about each of these generic drug research priorities for FY2024 available in the BAA announcement under charge 1, subsection C-J for that. We enthusiastically welcome research proposals that address

these priority areas and we really look forward to working with you to enhance patient access to generic products. Thank you so much!

>> Thank you for your presentation, we will now open the Q & A section for questions related to Dr. Raney's presentation and Dr. Jesse is the panelist who would be addressing any questions. Please note that you need to direct your questions related to Dr. Raney's presentation.

>> Ian Weiss: Hi, I just wanted to chime in for two seconds so folks don't feel we're ignoring them. We see there's a number of questions in the question and answer tool within Zoom. Just wanted to let everybody know that, as we go along as questions come in for this specific presentation, we'll be addressing them after those particular presentations and these more general or contracting questions, we're going to kind of defer until the end, to the big Q & A in the end. So please, if you have put in a question, don't feel we're ignoring you. We do see them. It's a big question and answer session in the end. Thank you!

>> Thank you, Ian for that. I do see there's a question with regards to, the GDUFA characterization based approach. That was covered in Dr. Raney's presentation right now so if you have any additional questions on that, let me know. Otherwise, that presentation did cover one of the GDUFA areas for the science and research priority initiative for this year under complex products is covered.

>> I have a question regarding the proposals that address the items in the generics division, that has already been addressed.

>> Thank you, yes, anything that related to generics and drug development can be sent with charge 1, Dr. Raney mentioned in his presentation, is covered in the BAA announcement of charge 1, subsection C-5 and all of the items he spoke of are covered for the generics program area that we are covering for the GDUFA program under C-Y under that area announcement. I do see some questions specific here in the chat such as developing skin penetration robustness, an area of interest. So yes, that would be something to be considered and you should submit that if you are interested in this area. You're welcome! I see other questions here I'm going to try to address here. In terms of the proposal to cover multiple items listed, for example, under the nitrosamines, are we looking for a proposal to cover a single item? That is a little bit more detailed. I would suggest you submit your proposal and feedback can be provided but at this point, I can't be specific in terms of single or multiple. The slides will be available after the meeting. They will be posted on the website. I.

>> Any other questions specific to generic drugs I am not seeing?

>> Do you think this is relevant to your office?

>> 125? Let me see here. (Inaudible). That's correct. So for clarification, let me reread the question so I'm addressing it correctly. So for clarification based on the topic area overview we just shared with you, the goal being that FDA can obtain new ways of testing and validating products that go through the FDA for clearance approval, not for industry to share new devices and therapeutics. So this is in the area of research so we're looking for research proposals to advance the generic drug product arena. So yes, sorry, I lost that question. So to address specifically, sorry. I'm not sure what is going on in the chat.

>> We can provide an answer later. All answers, all responses to the questions will be posted on the event page. And there's another question, are proposals for

developing methodology to improve clinical diversify of that --

>> In this arena, I would say yes, you may submit it. We do cover clinical trials within the submitted areas. It will depend on the proposal in which you determine. Yes for that area, you may submit that methodology for the clinical trials.

>> And this would be the last question that we would be taking at 1:27 p.m., Jesse. Recently CRCJ posted an opportunity on DDS addition, would areas around this be encouraged in the behavioral process? Would that be relevant?

>> Yes -- and topical products are still relevant so I would encourage you to submit a few if you have any areas of interest. The CRCG posting is for a grant versus this process is for a contract. So there are two different pathways but again, we will assess on the merit of the proposal and if it aligns with our priority areas.

>> Thank you!

>> Great, thank you!

>> So with that, I would like our AV team to play the next presentation from Dr. Kimberly Maxfield.

>> Kimberly Maxfield: Thank you for listening to my talk. I am the scientific lead for the BSUFAIII regulatory science pilot program. I will talk about how this relates to the BAA announcement.

For a very high level overview, here is the state of biosimilars at FDA. As of October 5th, 2023, CDER has received meeting requests to discuss the development of biosimilars for 54 different reference products. FDA has approved 43 351K BLA for biosimilar products, 6 of which are interchangable and according to our data, 38 have been marketed. On bottom of this slide, there's a couple of links about cost savings which is the main goal for biosimilar development and marketing. I won't go over it today but here's some links that you can look at.

Despite these successes, there's many challenges and barriers for biosimilars in the U.S. the overall arching goal is to increase access to expensive medications and lower the cost. However, across a biosimilars life cycle, there's challenges around all of this. For the FDA we're really focused on the cost and time to licensure. Due do this challenge as part of the BSUFA enhancement areas, leveraging -- excuse me -- leveraging regulatory science to move biosimilarity forward is an enhancement area.

Specifically, there's a commitment included in BSUFAIII, where FDA committed to enhancing regulatory decision making and facilitating science based recommendations in had areas foundation to biosimilar development. There's two demonstrate products or aims included in the commitment letter. One, approve the efficiency for the biosimilar development and advance interchangable products. Now these demonstration projects and aims are very broad so in the beginning of the pilot program, we brought together a form of FDA SMEs in the disciplines of biosimilarity and decided to focus the program on the competition of the 351K data package. So on the left of the slide, you can see the current data package that is generally submitted as part of a 351BLA including product quality, comparative analytical assessment, clinical pharmacology and comparative clinical studies. Through program experience, policy development and the regulatory research pilot program, we hope that the potential future of pathway will increase its reliance of a demonstration of biosimilarity on analytical data and will leverage alternatives to and reduce the size of studies involving

human subjects. As such, these two were set as a program goal and as part of our research road map. Of note, our research road map is under revision. The current road map, the first draft is being revised and this is the current revised wording. With these program goals defined, we were able to define research priorities under each goal. So for the first goal of regulatory impact, increasing the reliance of a demonstration of biosimilarity on analytical data.

Explore how modernization of analytical technologies could better and/or more efficiently detect relevant quality attributes can and three, define best-practices for reporting and assessing quality attributes.

For our second program goal or regulatory impact, developing alternatives to and or reduce the size of studies involving human subjects, again, we have three research priorities. The first develop alternatives to the comparative clinical immunogenicity assessment. Two, define the development approaches that will increase feasibility and or likelihood of successful biosimilar development and three, identify user interface differences that will likely lead to differences in use error rates or use success rates in the context of pharmacy substitution.

Now I have read out the research priorities from our draft road map for the pilot program, you may be wondering how does it relate to the broad agency announcement. Because we are in the middle of revising our road map, we didn't want to include language that had not fully been through the revision process so you can see here, the first three columns include the topic, the priority area of the topic and the priority included in the BAA announcement under 1 modernized development and evaluation of FDA regulated products. We have A alternative methods, C analytical and computational methods, had, methods for assessing behavioral, economic, or human factors and H methods to assess real world data to serve as real world evidence. We have included the language here, either directly from the BSUFA and mapped it back to our draft priority so anyone who is looking at submitting a white paper or concept paper under these priorities, can reference these slides.

Lastly, for any additional information about the regulatory science pilot program, please e-mail us at this e-mail here and there are additional resources that biosimilars, at FDA.gov. There's the biosimilar science and research page which has a lot of activities that the program is doing and then last week, we actually held an SBIA Webinar that has an update on the regulations side program and those slides and that recording is available at this link as well. Thank you so much! I'm happy to take any questions during the Q & A. The.

>> Thank you for the presentation, Dr. Maxfield. I invite questions related to Dr. Maxfield's presentation.

>> While we're waiting for questions, when I recorded that, the slides and the recordings for the SBIA meeting on the 16th actually aren't up yet. We thought they would be by today, but they should be up by Monday. So if you're looking for that, check early next week.

>> We can give our attendees another minute to see if they have any questions.

>> I see a question about the website that all of this is posted to. I am assuming this is referring to the research priorities for the BE regulatory science program. If you actually Google biosimilar FDA science and research, it should be the first hit and if you scroll all the way down, there's a lot of information about our funding cycles, links to our

previous meetings, information about the awards that we have provided.

Hold on. Can interchangable -- here's a question. Can interchangable processing of the same product be considered under this program? I'm not 100 percent sure what processing means. Jesse mentioned this is the research side so it's knowledge gaps, approaches and information that when filled would achieve the goals we outlined increasing the efficiency of biosimilar development and advancing the interchangable products. This is not a product specific program. I think that is everything for me.

>> Thank you for the presentation, Dr. Maxfield. We will now proceed with the next presentation. I would like request the AV team to bring up our presentation from Dr. Lee.

>> Dr. Lee: Thank you! Good afternoon, I'm Dr. Michelle Lee, a regulatory science manager and today, I'm briefly highlighting regulatory research interest to CDRH. Please note, this highlights only some of the CDRH area of interest for the solicitation. For more information, please refer to the full BAA solicitation document and the resources contained within. The research areas I will be highlighting are found throughout the BAA solicitation. The slides are grouped together by overall topic and includes streamline language from the solicitation. I hope this format accompanied by my description of the connections between research topics helps paint more detail picture of CDRH regulatory science research areas of interest. And finally while this presentation focuses on BAA, we at CDRH are actively engaged in partnerships outside of the BAAs. Like, projects in public and private partnerships. We look forward to continuing the work with stakeholders across the ecosystem to advance regulatory science. Next slide.

This slide displays the list of the main categories that I'll be highlighting. I'll start with health equity. While this is listed here as an individual category, you'll notice that health equity is a theme that runs through many of the other research topic areas I will describe as well. Advancing health equity is one of the three CDRH strategic priorities for 2022 to 2025. This priority recognizes that CDRH can advance the development of knowledge and safe and effective technologies to meet the needs of all patients and consumers across diverse populations and demographic groups. Next, I would like to highlight several areas that are the agency's goals, patient science and engagement, development of real world data and real world evidence methods and expansion of digital health expertise. Following, I will elaborate on topics that are important priorities year after year. Regulatory science research, in vitro diagnostics and advance manufacturing and quality. Finally, I will finish up with some topics particularly relevant today, relevant counter measures and building a resilient supply chain. Next slide.

As I mentioned previously, advancing health equity is an overarching goal for CDRH and there's many different areas of research that we seek to involve in achieving this goal of meeting healthcare needs for all U.S. patients and consumers. We recognize that sometimes there's a lack of evidence to know whether an existing product benefits one demographic group similar to others. And that medical innovation deserts persist for conditions that predominantly effect diverse populations particularly racial and ethnic minorities. That's why we're interested in an intervention specifically designed to enroll diverse population ins clinical trials. For example, using digital

health technologies in decentralized clinical trials or the use of remote assessments on under represented subgroups. We're also interested in changes to clinical study design and conduct once the trial is done. For example, how do we retain study, once they're enrolled. And finally, not only are we interested in the interventions but tools on how to evaluate the effectiveness and impact of the interventions and the last thing I will mention here, diverse and under represented, can also include rural populations. Pediatric and elderly populations and tribal populations among others. Next slide.

Communication to patients and consumers is one area where health equity can be interwoven. We at CDRH helps to better engage and empower them to be involved in their healthcare decisions by helping them understand what risk is involved with the use of FDA regulated products and when product recalls are issued. To do so, we need to make sure that all patients and consumers are able to comprehend the content of publicly issued communications and labeling. This includes digital literacy or even limited English proficiency. We're interested in the development of tools for measuring the effectiveness of messages communicated to the public and also best practices for FDA communications including the level of detail, formatting and delivery strategy of messages. Next slide. Another way that CDRH seeks to involve patients in healthcare decision making is through patient science and engagement. Patient input is critically important throughout the total product life cycle for medical device development, through regulation and device use. Past CDRH guidance has discussed including patient preference information or PPI and patient reported outcomes or PROs and we continue to be interested in these and other validated methods for collecting patient input and experienced data for use and device evaluation. For more information on the work of CDRH patient science and engagement program and a list of priority areas where CDRH would find patient studies informative, I have included links on the slide for distribution. Next slide.

My next topic is real world data, real world evidence, and clinical trial design. Real world data is data related to patient health status that is collected from a variety of actively and passively generated sources. Such as electronic health records, claims in billing activities, product and disease registries, or patient generated health data from wearables and home use devices. There's many benefits to collecting can and utilizing it and CDRH is interested in supporting the development of new tools and methodologies to harness real world data. This can also be integrated into novel clinical investigation designs that rely on telemedicine and other decentralized approaches that can help us reach a wider variety of eligible participants including those from underserved populations. With those many benefits come also very important considerations when gathering and utilizing real world data to support evaluation of medical devices. We're particularly interested in tools and standards for assessing data quality, uncertainty or bias, interoperability, and utility of real world data.

In addition to successfully leveraging real world data and subsequent real world evidence, we work for data infrastructure that facilitates information exchange and data extraction across multiple sources. Next slide. Much of the technology that helps us capture, transmit and analyze real world data is digital health technologies or DHTs. CDRH is very interested in the role that DHT can play in medical product device development, performance, and monitoring. As digital health technology matures, we're interested in ensuring transparency around the use and also managing bias in the way

that data is collected and analyzed. Especially in the case of artificial intelligence. These are rapidly growing fields that are being incorporated into more medical device technologies. CDRH is interested in methods to assess algorithm performance and tools to evaluate the performance of large language models or yen generative AI models as applied to medical devices. Next slide.

So I previously mentioned this but it's worth mentioning again that digital health technologies can play a significant role in enabling decentralization of clinical investigations and remote data collection. The facilitating the enrollment and retention of populations that may not typically be reached with a traditional clinical investigation. CDRH seeks to understand and better evaluate the ways that DHTs can be used in remote data collection, particularly for under represented subgroups, like rural pediatric, elderly or tribal populations and also patient groups who may need extra support to stay engaged in their treatment programs like those struggling with substance use disorders.

Next slide. Another important source of real world data is in vitro diagnosis or IVD. CDRH is interested many exploring how to capture, transmit analysis of high quality diagnostic data from IVDs in real world settings and the utility of that data in the evaluation and surveillance of other medical products. Through the COVID 19 public health emergency, we saw the important of IVD in informing decision making in the form of at home COVID-19 tests. Moving forward, we look to support research on enhancing data agility and quality to make sure we're prepared to meet the future healthcare needs of the American public.

IVD data can be incredibly helpful in predicting medical device performance, disease diagnosis and prevention. But in order to do so, we need to make sure that the data can be analyzed in combination with other patient health data, synthesized for multiple purposes and that's why CDRH is interested in supporting research to improve among harmonization and generation of interoperable, diagnostic data. Next slide.

Moving on to our next focus area, advance manufacturing and quality is also an important topic when it comes to supporting public health. CDRH supports regulatory science research that explores how advance manufacturing can further improve the development and production of medical devices. This includes evaluation of automated, in process monitoring and control systems and validation of digital technologies like computational modeling and artificial intelligence or machine learning for use in product design as well as quality and risk management.

We seek to support regulatory science and research that prepares the device manufacturing industry to be agile and responsive to emerging public health needs and I look forward to seeing proposals on improved methods and tools focused on harnessing these methodologies and making advances in the study of quality management maturity and organizational excellence. Next slide.

The past several years have shown a spotlight on the importance of preparedness in public health. My last topic is medical counter measures and building a resilience supply chain. Medical counter measures or MCMs are FDA regulated products that may be used in the event of a potential public health emergency, for example, personal protective equipment or diagnostic tests. CDRH looks to support multiple topic areas around MCM such as enhanced data, agility of data collection through MCM, rapid development so they're available when we need them the most. We also seek to support the development of novel approaches and technologies that

enable MCM suppliers to be flexible in the occasion of supply disruptions or to build up the chain within the U.S. L additionally, when shortages or device recalls occur, we seek to better understand the risk to special populations within the U.S. when they're unable to access medical devices as usual. Next slide. Thank you very much for your attention as I covered some highlighted regulatory research areas of importance to CDRH. We sincerely look forward to receiving your proposals over the next few months. Thank you!

>> Thank you for your presentation, Dr. Lee. I would like to open the Q & A pod for questions related to Dr. Lee's presentation. I did see a question in the chat. What are the priorities in terms of disease areas for CDRL?

>> Would refer to the BAA, I don't think we have submitted priorities in terms of disease areas but over all topics. I would refer to the solicitation to see which areas are of specific interest but in general, we did not separate our priorities out per disease area but I think, across disease areas, if there is specific research that you're working on related to medical devices, that pertains to the general topics. For example, the ones I can cover, like digital health, advanced manufacturing, patient science and engagement, health equity, we're interested in proposals across all disease areas that are related to those topics.

I do see another question for the medical counter measures. Are there modalities that are of priority, for example, microbiome, versus vaccine? I don't think we have specified certain modalities of priority. I think being CDRH, we would review the proposals for medical counter measures that are specifically related to medical devices of which, you know, vaccines may not be under that. So I think, as long as they relate to the general priorities under MCMs, we would be interested in them and as long as they relate to medical devices.

I do see another question. Will advanced manufacturing and quality focus on devices or also pharmaceutical manufacturing is of interest as well. I would defer it to my CDER colleagues but for our center, we will be reviewing the proposals that have to do with medical devices and I think, there might be more information on this later but, some of the proposals are also joint reviewed by multiple centers. And so if there is, for example, a topic or proposal for advance manufacturing that relate to pharmaceutical and device manufacturing, it's a possibility that both of the centers will review this proposal.

I see another question, will CDRH support gene therapy, supply chain specific proposals? I think this is similar to my answer to the previous question. Gene therapy being more related to CBER. The again, if there's proposals that relate to multiple centers, we may do a joint review.

>> There's a question, Dr. Lee, but I'm not sure if it's specific for CDRH.

>> Which question?

>> Do you prefer to work with single academic center or consortium of multiple in.

>> I see. I don't know I can speak for other centers but I do think that we don't have a preference regarding who is submitting the proposal or who is collaborating on the proposal. We welcome proposals that are from single academic centers or multiple academic centers.

>> Thank you for your presentation and serving as a panelist, Dr. Lee.

>> With that, I would like to request the AV team to bring up the next presentation for Dr. Julie Schneider.

>> Julie Schneider: Great, can you hear me? Okay, great! Good afternoon, everyone! I'm Julie Schneider from the oncology center of excellence and thank you very much to the BAA day presenters for inviting OCE to talk today. The purpose of my presentation is to provide a brief introduction and overview to the FDA oncology center of excellence, explain our interest and participation in the BAA program and very briefly introduce some of our scientific priorities. Next slide, please.

The OCE is a relatively new center at FDA. It was established in 2017 under the 21st century Cures Act. Our mission is to achieve patient centered regulatory decision making. OCE is responsible for the clinical review of oncology therapeutics and we work across the FDA centers that are active on oncology, such as the center for biologics or CBER that regulates things such as gene therapies, therapeutic vaccines and oncology. The center for drugs or CDER that regulates small molecules and biologics such as monoclonial antibodies as well as antibody drug conjugates and the CDRH that is not just therapeutic, but also in vitro diagnostics such as companion and complimentary diagnostics that are important in precision oncology. Next slide, please.

So regulatory review of oncology therapeutics is at the core of OCE work. As shown on the slide, we have programs in other areas including regulatory science, education, stakeholder engagement, and regulatory policy and our participation in the BAA program is part of our work in regulatory science. Next slide, please.

FDA oncology staff, I should say, is very active in scientific activities and publishing including publishing research papers. M and in general, they're very interested in collaborating with extramural researchers so to give you a sense of this, a few years ago, we did an analysis of publications produced by the oncology staff and we learned as a group, they publish about 75 to 100 articles a year. About 20% of the papers are summaries of regulatory approvals but many of the remaining papers focus on research and in general, we found these papers are very impactful. The this particular analysis revealed that the papers, these papers from FDA oncology are sited in the scientific literature about two times more frequently than the average NIH funded publication. Next slide, please.

So my main role at the OCE is to over see the OCE scientific collaborative. And the goal of the scientific collaborative is to support FDA's scientific staff to plan and conduct high quality applied research that addresses challenges identified during the regulatory review of oncology therapeutics and it's in general my understanding that the BAA can fund basic and applied research but in general, OCE prefers to fund applied research projects focused on improving specific aspects of therapeutic development rather than increasing general knowledge about cancer. Next slide, please.

So a few years ago, we took a look at the broad range of our scientific activities including publications, internal research projects, research collaborations with external institutions, meetings, workshops and through this analysis, we found there were nine scientific interest areas and one cross cutting area that we were very active in and they are shown on this slide. So these are by no means, the only area but it's areas where we have a lot of ongoing activity and have included them in the BAA announcement.

Because of the new BAA framework, the areas are interspersed throughout

the announcement but if you visit our OCE collaborative website on the bottom of this slide, you will see where they fit into the different BAA sections. Next slide. Some during the next part of my talk, I'm going to briefly introduce each of our scientific interest areas. Again, all of this information and more detailed information within each of these scientific interest areas are included both in the BAA announcement and our OCE scientific collaborative website. So in the areas of cell and gene therapies, we are interested in applied research projects that relate to clinical development, manufacturing, safety evaluation, and quality control of novel approaches such as gene editing base technology, cell therapy, and neo antigen based cancer therapies. Next slide. OCE is very interested in understanding factors that affect the safety and treatment response in demographic subgroups that have been historically under represented in oncology trials. Including racial and ethnic minorities, sexual and gender minorities can and older adults.

In the area of immuno oncology, we are interested in supporting this to that are unique to regulatory submissions of immuno oncology products such as understanding unique side effects and understanding atypical responses such as delayed progression or pseudoprogression. Next slide.

We have a very active research program in the area of oncology patient focused drug development and in this area, we are interested to support applied research about the scientific use of this, to quantify symptoms and function on oncology trials. In the area of statistical methodologies can and endpoints, we are interested to support research in the development of innovative approaches for trial designs or statistical analysis of oncology, clinical data. We are also interested in research addressing potential novel, early endpoints and in identifying and refining real world endpoints that could be used in clinical studies to inform regulatory submission. Next slide. In the area of oncology therapeutic safety, OCE is interested to support research to develop innovative approaches to allow rigorous analysis of safety signals throughout the life cycle of oncology therapeutic development. And to improve our understanding of toxicity. We are also interested in studies that use, that explore the use of real world data to inform post marketing safety. Next slide. We are also interested in support applied research to accelerate the development of oncology therapeutics for children using multiple approaches including the development of new clinical models, novel trial designs, and the use of real world data. Next slide. In the area of precision oncology, we're interested in applied research to develop and deploy biomarkers. For example, molecular or imaging biomarkers to accelerate and improve the regulatory a review on oncology therapeutics. Next slide.

In the area of rare cancers, we are interested to support research in novel approaches to support drug development in this area. For example, in areas such as drug repurposes, telemedicine, innovative trial designs and the analysis of real world data. Next slide. And so the final topic is really the cross cutting area and you have heard me bring it up in several of the other scientific interest areas I have described and that is around real world data utilization. And this focuses on developing approaches to evaluate, integrate, and facilitate the use of oncology real world data.

And then final slide, please. So this last slide, I want to provide a link to our newly created website that includes information about our active extramural projects that OCE is currently supporting and this includes projects supported under the BAA.

As OCE is a relatively new center, it's still a relatively modest number of projects but our ultimate goal is to build a research portfolio using the BAA and other mechanisms that addresses the range of scientific interest areas that I have described in this presentation. So thank you very much for listening and we very much look forward to receiving your proposals.

>> Thank you for the presentation, Dr. Schneider. I would like to open the Q & A pod for questions related to Dr. Schneider's presentation. There is a question we have. Dr. Schneider, do you want to take that?

>> Dr. Schneider: Let me just read it. Interesting. So this question is trying to get specificity about whether we would support research on bio informmatics pipelines. I'm not exactly sure what is meant by purely bio informatic pipeline development proposals. I think that, if it relates to -- if it's something that relates to, specific issues in terms of regulatory review of oncology therapeutics, we could, that would be something that we would look at. But I'm sorry, I think that's something that we probably need a little bit more detail to say specifically.

>> There's another question.

>> Oh! We have a proposal that could be relevant to two centers. I think the CDRH speaker answered this question which is, sometimes we do -- there will be multiple centers that might flag a proposal of interest and we usually both, you know, in many cases we would both get involved in the preview so I think that is fine and you know, OCE is certainly always very interested to collaborate with other FDA centers. Are you interested in therapeutics that can alleviate side effects such as colitis? Well, we're definitely interested many immune related adverse events as they apply to immune oncology, in general, we don't support research into specific product development. It's more needs to be more generally applicable across the oncology area. Oh, I'm not sure this is for me.

>> There was another question. How are you addressing where there seems to be overlap in subjects between this BAA and other announcements that use similar text?

>> I think in general, you know, the types of research that we're interested in supporting, you know, is not as I mentioned before, we're much more interested in applied research that is addressing topics that is very focused and related to regulatory challenges that are coming up. So we're not, you know, we're not generally interested in supporting research that addresses, that creates more general knowledge. Some of the broad topic areas are similar but we're very focused on applied questions, you know, that come up in regulatory review.

>> There's another question, what about radio active -- other areas for OCE?

>> I am not particularly familiar with that area. It's not included in our scientific interest areas but again, our scientific interest areas are just an example of the types of things that we're interested in. If it's related to oncology, therapeutic product development and it's important issue, and that argument is made in the proposal, it's likely something we would take a look at.

>> Does your center have interest in technologies that can aid in patient evaluation under telehealth?

>> Yea, I mean, I think. For us, everything is very oncology focused. I know for example, telemedicine is an area that came up under our rare cancer area in so far as,

if that could be a tool that could be used to help enrollment in trials of rare cancer. This is a more general question but for us, we're very interested in oncology, therapeutic development, oncology clinical trials and so if it applies to that area, it's likely that it's something that we would look at.

>> There seems to be similar language between BAA topics and NIH, should this be complimentary to those?

>> I think I already answered that one, didn't I?

>> Yes, you did. I think those were all of the questions.

>> Wonderful. Thank you so much for all of those questions, I appreciate it.

>> Thank you again, for your time, Dr. Schneider. I would request our AV team to bring up the slides for our next presenter Mr. Robert.

>> Good afternoon. Can you hear me okay? Outstanding, hi! I'm Robert and I'm a biologist and program manager here for the FDA office of counter terrorism and emerging threats. I want to give an overview and a few of our priorities for this afternoon. Next slide, please. To start with, our office is primarily aligned with the development or the availability of medical counter measures. Defined within the context of the broad agency announcement, these are products that protect against, treat, or diagnose diseases or health effects caused by chemical, radiological, nuclear threat agents. Next slide, please. So specifically, our mission is on the regulatory side. We don't engage in product development per se but we develop tools, standards and approaches under our medical counter measure. Program. And it's really serving the over arching goal of ensuring there's availability and agility to the development of counter measures and the development and availability of counter measures. We do it in a series of different kinds of funding activities. For extramural research which is what we'll primarily focus on today, that includes contracts. We do have grants but we'll focus on this today. We're going to talking about the difference between contracts and grants. There are other programs as well. There's the intermural research program in which other offices in FDA fund internal products conducted by FDA scientists and we have partnerships and collaborations with other government agencies. The funding vehicle for that is called the interagency agreement or IAA. We're going to come back to this in a minute.

Next slide. So let's focus on our OCET BAA contract. Just a point of order, I can speak to the history of this and I'm going to stay focused on that for today. Speaking to that, our OCET portfolio has been working with the BAA since 2012. We have seen throughout the history of the program, some commonality between the contracts and efforts we have supported. So BAA contracts, for example, they have a maximum of five years. Typically, we structure ours to be some sort of variation of a base and option format. Which is to say, we have a base period of a minimum of one year. We have had three year base periods. This is to achieve some sort of initial goal with an expansion by options for the remainder of the five year period typically. Now, do all BAA contracts for OCET extend for five years? No. This is just typical for our history. You are advised to structure it accordingly. So if you the ability to structure say a particular deliverable that aligns to a base period and expanding options, that might be a good way to organize things when you submit.

Our BAA contracts are managed in house by a team of personnel similar to me. That is to say, we're both subject matter experts, biologists or scientists in some

sort of discipline related and we also serve as CORs so we have both mechanics and sort of the technical direction elements. The we typically use monthly meetings can and either monthly or quarterly reporting periods to do that oversight. Now, our contracts are considered high complexity as it's defined in the contractor performance assessment rating system, CPARS and we use cost reimbursement because this is R & D.

I mentioned interagency agreements before but we do partner with other government agencies for both the review and for potentially funding opportunities on a given proposal. So if there is some sort of proposal that aligns to multiple government requirements or priorities, we will use this to co fund. If we do that, one thing to keep in mind is that we will need to get the funding mechanism in place before we can move forward with it. So that may adjust your timeline if you're seeking a contract award. Just keep it in mind. Again, the maximum period of performance is five years and our deliverables are knowledge products. I think that's very similar across the board here. We don't do widgets but we do encourage publications and presentations. Next slide, please.

I'm going to go through our BAA contract areas so this is listed under 3.A of the BAA. That's primarily pertaining to counter measures. . These have already been covered by some of my colleagues so we'll just touch on the ones that OCET in particular had a history with and we'll explore that a little bit more. So we're going to go through each one at a time, starting with the development of methods to support MCM development. So this includes a series of different approaches and that includes, sorry, to include alternative methods to animal testing. So that, I would say would fall under the development of micro physiological systems or in vitro systems as an alternative to animal testing that includes other alternative animal models. So if there's a product being evaluated and using a non human primate model, we would be interested in an alternate animal model that may be an alternative to that. We also look at characterization of disease progression but really, this is under the lens of medical counter measures of applied regulatory science research so not so much basic research but really focusing in on things like mechanism of infection, ability to determine morbidity, mortality, and sort of focus on the MCM regulatory science.

We also look at biomarkers and correlates of protection, either directly or sometimes more indirect if we're looking at more disease model but the bottom line is, we have a series of different objectives here. One of which to utilize or increase our flexibility and use of the animal rule. Since medical counter measure development tends to be very closely aligned to the animal role, we're looking for different kinds of studies that would bridge data between animal models, to more clinical base models. So next falls into diagnostic and diagnostic data. This branches to a couple of different areas. Next generation sequencing as well as the use of real world evidence. So we have talked a little bit and you have seen topic areas within the realm of real world evidence previously. In the context of medical counter measures, we have a history, a little bit of a history with real world evidence here and I will point to the last sort of bullet on the slide. That's, for example, looking at retrospective studies, evaluation claims data for the effectiveness of medical counter measures. We have a history with that. That also is available, and some additional information is on our project page which I will lead to shortly. But we also have an interesting different techniques such as the

next generation sequencing. The bottom line is, we're looking at different methods to enhance our agility for both data collection, for example medical devices but also looking at expanding our capabilities with diagnostic approaches. Next slide, please. Some this next slide or next area, actually, dove tails nicely. And this is our advance manufacturing team.

So we have a couple of different areas within OCET and the regulatory science research that we support. We're looking at different methods through the BAA to increase agility and our ability to potentially increase the speed of product development and availability. The best example I can think of for that is, some of the lessons learned from projects and received in response to the COVID pandemic.

So for OCET, what we're seeking here is the ability to identify technologies to carry out regulatory science and an evaluation of safety and efficacy. This also, however, goes to a different area which is really looking again at resiliency. And being able to increase resiliency for our supply chain, specifically as directed to medical critical counter measures. Now this last slide was covered previously. I will touch on it briefly because OCET shares an interest in these particular areas, specifically with our advancement of manufacturing community. So I know our CDRH team had presented on this but I will say that in the interest of just making folks away of multiple centers, I think, sometimes engaging in different topic areas, this is one that OCET has some interest in. Next slide, please.

To that end, we note there's some cross cutting areas of interest in the BAA and advance manufacturing is a very good example. The so we noted that there are advance manufacturing criteria elaborated here but I will just add that when there are medical counter measure use cases in association with advance manufacturing concepts, that is something that we would actually focus in on and would be willing to do sort of a collaborative evaluation in review. So from a standpoint of submitting a concept to the BAA, if you see an opportunity to identify a medical counter measure related use case, it may be something to highlight because it will increase your impact and thus, may increase the prioritization within the review paradigm.

Moving on, next slide. Okay, so this is a list of our ongoing projects. So I'm going to go through this very quickly. So all of these projects have individual project pages that are available on our website but we did do a couple of classification items here, mainly, we did provide information with regard to the specific BAA area they were submitted under. In some cases, these were submitted in prior to the new sort of classifications so we had to do a little bit of a crosswalk. That being said, these are the projects under way currently. Next slide, please. My goal here is to show and provide a snapshot of what we have available. These are project titles. If you want to get into the detail of what these projects are doing, or what the objectives are, I would strongly encourage you to check out our extramural regulatory science research page and I will have a link to that in the end of the presentation. Next slide, please. These are the completed projects, just trying to get a sense of the history and portfolio. So you will see that these have, that these are completed projects. We provided date of completion and what I really want to draw down to here is, just some of the different themes and topic areas that we have prioritized and emphasized over the history of the program. And these are more completed projects so you can see there are some related to the specific diseases. We have also had some related to PPE. Some related to real

world evidence. Next slide.

And yes, these, that's more completed projects. We have an extensive history going back to 2012, next slide, please. So we do have, I want to just touch very briefly on our successes and what we see as successes of the portfolio. So from a practical stand point, 19 contract awards. We have worked domestic, international, and I know there's some partners on the line today. We have received counter measures that can be tricky given the usage of the animal role and just, by nature of this subject area.

We have also seen the problem as realized over 115 publications and that's just from the current performers and doesn't account for the prior completed partnerships. Going back to the IAA, you can see where we partnered for contract awards and we have even this, included an example here of some intramural partnering with our office of minority health and health equity and in this case, for diversity within a COVID study. Next slide, please.

This is historically data. I'm not going to talk to current projections or any current funding but I can provide a history of our previous awards. Awarded projects.

This is broken out here. If you have questions, we do include funding totals on the individual projects we have awarded but it helps to give a sense and the historical context on what we have awarded and what the range has been. Next slide, please.

Finally, these are some of the particular successes from a regulatory standpoint from the work we have sponsored due to the extramural program. This goes through the work we have done in response to the Zika response and the PPE. We see what emerges from BAA as particularly impactful and my office is happy to support it, either individually or as part of a group within FDA. And with the other offices or centers. Next slide, please.

And this is, this is actually our regulatory science team. This is my last slide. I'm going to show you a link to our medical counter measures page here. And we are definitely interested and welcome your proposals and I'm eager to address your questions. Thank you!

>> Okay, thank you for your presentation. With that, I would like to invite the attendees to pose their questions in the Q & A pod. Q&A pod. If you have posted a question and you have not received your answer, please note we will be addressing that question at the 3:30 Q&A pod session. So you have questions coming up?

>> So first one, I think for me is, do we require these strains for research or are you -- BSL surrogate strains okay, or is it proof of concept? I can answer from a historical context but I need to say the caveat, the approach along these lines will boil down to ultimately the technical review but I can say from the historical perspective, we have supported the use of BSL to surrogate strains, certainly through the intermural program as well. So that is something, from the historical perspective of a portfolio, that answer is yes. The it would be contingent on particular, concept technical approach and likely, aging considerations too.

>> Do you support clinical trials of MCMs and on that, it would depend on what you mean by support? Traditionally, we do not have anything targeted to supporting clinical trials through our -- so we don't have extramural portfolio or projects that are

directly designed to support a clinical trial. We have projects that have involved such things. And so it really kind of depends what the context would be and what the other all technical approach is.

>> We have a question, would on demand GCF manufacturing be of interest?

>> On that one, I would have to defer to my colleagues in the advanced manufacturing community so if my understanding is that, that would be of interest. But in terms of this specifics, for a specific question, I would really need to defer and get some sort of a technical question on that one. As far as like approach and that would likely be something better addressed by my colleagues on the ANDA team.

>> This is such an interesting topic for FDA.

>> So COVID-19, so as we're all aware, the COVID public health emergency has been -- is technically at the end. However, we do still have ongoing COVID-19 projects which you can take a look at the project pages on our extramural page. We see COVID-19, potentially. If it's developing, if it's being used as a use case, potentially for developing some sort of capacity, maybe a way of developing datasets and agile data, it could be used for consideration. I will point out that dedicated COVID specific funding has also ended as a result of the end of the public health emergencies.

>> Does your center have interest for technology in distributed manufacturing of vaccine products?

>> Well, I think on that one, that is something we have included in our BAA language in the past. Our office, specifically, however, has not supported that particular topic area and that's not to say we don't have interest as the FDA. But I can only really speak to OCET's level of interest.

>> What types of supply chain resilience topics are of highest priority?

>> On that one, this would be something that we would have to defer to our advance manufacturing team. And it may vary. Advance manufacturing as well as supply chain resilience is topic areas, they are cross cutting topic areas and stretch over multiple offices and centers frankly so prioritization is going to vary as well. Bottom line is, my suggestion is to submit the concept paper to address what area you're sort of driving at. We can make an assessment from that perspective. Is 3 D printing a counter measure, as a method for -- counter measure production method of interest?

>> On that one, I would say that it would align to some of our advance manufacturing related topic areas so my suggestion would be to submit a concept paper and we would be better able to evaluate it on the specifics of the technical approach. Next, would you consider proposals for the development of novel NGS based diagnostics and if not, can you give an example of the types of tools you're looking for, or whether the enhanced NGS based topics applicable?

>> I can do better. In short, the answer is yes. We consider the development of novel NGS based diagnostics. In terms of an example of providing reference points any way, I would strongly suggest that you check out the project page, specifically the projects that we have that are indeed related to NGS that will provide a lot of the examples in context that I think you're looking for.

How do you see large language models impacting proposals? That's an interesting question. I think it could be a factor. The question is, does it align with an approach? It's applied through the MCMI lens needs to have an MCMI use case or specificity for some sort of medical counter measure. I think large language models

could be utilized under the auspice of real world evidence but it depends on the context of the use case. Are you interested in modeling advance manufacturing? Again, this is another one I need to defer to my team for specifics. Modeling is something that historically has been at least evaluated successfully as a concept, like, technically there's white papers previously but in any case, it has at least some potential impacts but it really, boils down to use case where you see that sort of see the modeling being utilized. We don't typically look at modeling within the context of epidemiological methods but for advance manufacturing, for supply chain resiliency, that might be something. It just really depends on the context of the submission itself.

Are novel surrogate endpoints to advance interest in yes, based on the history of the program, you can see that we do have some portions with our intermural and extramural program. How to submit a concept paper? On that, I will defer to our next.

>> We can take that question. How can we get information from the advance manufacturing group? The best way is, my contact information is provided, I think in the materials. If not, you can look me up. It's relatively easily or get it through the folks. But best is to reach out to me directly and I can put you in touch with this. Keep in mind, this is our advance manufacturing team for OCET specifically.

Which type of advance manufacturing process is of FDA interest, solid dosages or liquid dosages or both? Again, that is one I would have to defer to my advance manufacturing colleagues and I don't want to speak to FDA level of interest within the context of OCET. There is a need. The BAA is designed that advance manufacturing concepts occur in different areas and that's for a reason. Really, if it's of interest, that is something that is only what of a nuance question that needs to be evaluated from different perspectives and sources. The great part is, the BAA enables us to do that. If you submit a concept paper, something that multiple communities will weigh in on or have the opportunity to weigh in on to ascertain a priority.

>> So will the answers to the manufacturing questions be posted after you follow up with your colleagues? That I would have to defer to. To you folks.

>> I can get it posted if there's a response for that.

>> And I'm happy to serve as this. We can get that in writing.

>> Sure, let's take one last question for the presentation. In the scope of real world evidence, is there any specific areas of research that have more need than others?

>> More need than others? So we, within the realm of OCET, we definitely had an interest or we prioritized the ability to do medical counter measures specific studies, so looking at different effectiveness, we have done it through an initiative and also, a completed project with USC that looked at this particular topic area.

So relatively speaking, anything that involves the medical counter measure, related use case is always going to be prioritized from our perspective. I don't want to speak for the FDA centers but I don't necessarily see topic areas that are more of a priority than others. But I do think that contacts and overall concept of operations is important. Being able to point to a larger capability that may be developed within the general national strategy, that would convey a lot more priority than anything else.

>> Thank you so much for your presentation. And I would also like to thank you as a panelist for the Q & A session. I would like to invite our next speaker, captain

Skinner to present the priorities for one health. AV team, can you please present slides?

>> Skinner: Thank you very much! My name is captain Skinner and I'm in the office of counter terrorism, emerging threats. I also serve as the operations lead for the FDA one health steering committee along with my colleague on this presentation here, Holly and we'll be discussing one health BAA overview and priorities. This is the first year that one health has been included in the BAA overview. I'm happy to be able to present this today. Next slide, please.

So let's talk about, what is one health? So one health has been defined in many ways. What you see on the slide is the U.S. government accepted government. And if you look at any of the one health definitions, the main point is that one health looks at the intersection of human, animals and environment, usually that triad includes plants as well. The U.S. government definition has plants in it. So for the most part, the newly accepted definition is what we'll be using, even though when we first started, it was only the triad that you see here, human, animals and shared environment. Next slide, please. So how do we utilize one health in a framework? Basically what you do is you look at components of topics relevant to each of the domains involved in the one health concept. So you're looking at human health, animal health, and environmental health. And see how the topics intersect, whether they have commonalities. Whether they have correlations or what is the context of the commonalities and what impacts do those commonalities and correlations have? And then you want to include the social work ecological approach, and looking at this in the context and impact. So on the micro level, you want to look at levels on how it impacts individually, interpersonally, at the organizational level, whether it's a group or coalition or unit or at the community level whether these are organizations, institutions, or regional communities.

When you look at the macro level, you want to see how some of your one health topics needs relate to state, regional, national or global level, laws and regulations and policies because they affect masses, are considered macro level and then also, in a larger scale, you want to look at society and how it relates to cultural beliefs, norms and practices and ethics. The next slide, please.

So the one health approach is used at FDA because it presents a more holistic view of FDA's mission. So the convergence of one health activities already exist in FDA but when you consider the agency's responsibilities and authorities, it does include a human, animal and environmental health aspect. So this effort to improve health within regulatory science, goes beyond recognizing disease transmission of human health but it also acknowledges human animal interactions and associated environmental drivers such as physical factors, socioeconomic status, behavior and social determinants.

And the agency fulfills this mission for the benefit of both people and animals by ensuring the safety and efficacy of regulatory products, such as human and animal food feed, human biologics and this includes biologics that are derived from non human animal sources, and human and animal medical devices and radiation emitting products.

The agency also regulates manufacturing and markets and distribution of regulated products to ensure safety, equality standards are met that are beneficial to both people and animals. FDA also encouraging collaborations that embrace,

innovative technologies, beneficial for peoples and various species and environments they share so the agency coordinates regulatory pathway measures, fostering advancement of medical counter measures. The diagnosis, prevent, protect, and treat conditions, derived from intentional and non intentional emerging threats of chemical, biological, radiological and nuclear materials and these types of threats do not hold boundaries and can adversely impact peoples and animals alike in a shared environment. Next slide, please. So FDA's one health initiative began in 2019 when the FDA acting commissioner announced so this slides depicts the agency wide engagement with representation from all nine centers and offices that are a part of the agency's one health steering committee.

So the division and mission that provides FDA's overarching perspective in utilizing one health within the agency, is listed here and how it plans to do it. The so FDA's one health mission is optimal public health outcomes for humans and animals in their shared environment and our mission is that FDA collaborates with stakeholders across disciplines, and sectors to promote the health used in science, technology and innovation. Next slide, please.

So on the next two slides, I'm going to go over one health priorities missioned through the office of the commissioner and within the various interest of FDA. So this slide shows messages sent from FDA's office of the commissioner, on the social media platform formally known as Twitter, and one health is listed as a priority in the call of action for bio science communities and clinical communities. So please take a notice to one health being mentioned in relevance to data sharing and protection of data, national and global surveillance as well as antimicrobial resistance. So last year, FDA surveyed all of the offices to determine what were there one health priorities. So this list shows the themes that were collected from that survey. Notice, a lot did coincide or align with the FDA's regulatory mission.

So product safety topics, antimicrobial resistance and pandemic related topics, were the top three priorities that were themed from that survey with the priorities of technology, innovation practices, regulatory enforcement topics, and building capacity and resource needs. They were a sub category for the top three. Next slide, please.

So when I say these are examples, these are just examples of FDA's one health activities so they're not all inclusive but I just hope that listing these examples will give you some indication on how FDA uses the one health approach. FDA has been doing it for a long time even though it was not called one health.

So FDA uses one health by utilizing safety data to establish policies, standards and guidances as well as supporting and developing technology and innovation for products it regulates. It also uses a one health approach for education, communication and training relevant to FDA's regulatory mission. And the last example of how FDA utilizes the one health approach is through research and surveillance, used to respond and counter issues that are emerging threats to both humans and animals in a shared environment by supporting the development of products that FDA regulates.

This slide is to show you what we're looking at to review several projects. So first, look at the blue font information on this slide, these are the proposals we say are a must. All of the others are a should. So if the proposals are a must and you do not meet that criteria, we will not consider it for one health. So the proposal must utilize

the one health approach. That's first and foremost.

Next, it must align with FDA's regulatory mission. So even though it may have one health in it, it does not align with FDA's regulatory mission, that will not be considered for one health.

Other things you may want to also include is, it should align with FDA's one health vision and mission. It should align with the authority and if it includes cross cutting and multi-disciplinary actions and across the centers and offices, this is also helpful. Next slide, please. So for more information about FDA's one health activities and these are the links that can link to the web pages, Webinars on the internet and I hope you can get more information about one health there. I don't have statistics or background information since this is the first year we're doing this. Next slide, please.

So that concludes the overview of FDA one health. I want to thank the FDA BAA day planning team for the opportunity to present a brief overview of one health at FDA. And FDA's one health interest in BAAs proposals, I will take any questions you have right now.

>> Thank you. Captain Skinner. You have a question there. It says under the one health approach when cross cutting, develop the methods to assess the impact of contaminants on human, animal and environmental health, including the distribution and fate of the contaminants and the natural ecosystems and develop tools to better assess risk and predict sources on how this can affect the safety of medical products and human and animal food. If this is looking for a model tool or would a review of a biological contaminants, distribution and environment be of interest in.

It definitely could be if it uses the one health approach and some of this may also coincide with some of the other areas that is of interest but I would have to leave it up to the reviewers but for the most part, if it uses a one health approach and aligns with the priorities, that will be taken into consideration.

>> We have another question, captain Skinner.

>> What if the proposal addresses FDA regulatory needs as well as CDC mission? Can a proposal be co submitted, co funded by two agencies through some kind of interagency agreement? I think I have to leave it up to our OAG staff. I'm not sure about the funding part. I know so far as your submission, if it's of interest and the reviewers feel this is a priority, that could be something that we could question and ask for them but I would have to leave it up to OAGs.

>> Thank you very much, captain Skinner. With that, I would like to invite the AV team to play the presentation for our next speaker, Dr. Joyce Obidi.

>> Dr. Joyce Obidi: Thank you, everyone for being here today, for FDA's BAA day. I am Joyce Obidi, health program coordinator in the office of womens health and I'm happy to speak to you about the research priorities for our office. I thought I would start by giving a brief background on the office and our research program to help you better understand our research goals.

FDA office of womens health is established in 1994 to help promote the inclusion of women in clinical trials and to encourage the completion of sex and gender analysis not only for the study submitted to the agency but also for research performed by FDA scientists. A major part of our work is to identify and monitor womens health initiative and emerging topics in womens health as they relate to FDA's regulatory

mission. And then we serve as the principle advisor to the commissioner and agency leadership on scientific, ethical and policy issues related to womens health can and sex and gender differences. I just mentioned sex and gender. In the next slide, I will take a minute to talk about these terms and what they mean because you will see in the scientific literature that many people including academic researchers use these terms interchangeably. I urge you to recognize these terms as distinct and understand that sex and gender are not the same.

In 2001, an institute of medicine report defines sex as the classification of living things according to their reproductive organs and physiological functions assigned by chromosomal compliment. Sex is a biological variable that is typically binary and we refer to the two sexes as male or female. Whereas, issue gender is a social construct. It's influenced by the individual's environment, society, and culture and it's considered across a wide spectrum from masculine to feminine. And so the terms we use when describing gender, man, woman, something else. So this is the distinct concepts that are interact and interrelated but in thinking about FDA work for the most part, FDA works in the biological realm so for example, when studying the pharmacokinetics of the drug, you may see differences by sex but some of our work is gendered.

For example, studies with PROs where a person's diet or their response to pain may differ by gender. The biological variable is sex. Sex matters in biomedical research because males and females are not the same. There are the obvious hormonal and anatomical differences and the hormonal changes that occur with reproduction, however, there may be other differences with drug metabolism, safety and efficacy that cannot be solely attributed to hormones. Just as an example, this slide shows well established sex differences as seen in infectious diseases, inflammatory disease and cancer. At the extremes, male and female show robust differences in susceptibility to different diseases. Generally, females show increased susceptibility to autoimmune, and males show it to non reproductive malignant.

Therefore, sex should be considered when designing and analyzing studies in all areas and at all levels in biomedical research. That includes studies not only at the cellular level, every cell has a sex, but also for studies involving animals and humans.

OWH sits in the office of the commissioner. This allows us to work across the agency to progress the health of women by funding center research, being heavily involved in policy development, providing professional training and education to FDA scientists on the importance of considering sex differences in their work and developing consumer information for women and their families. This is a high level overview of office of womens health scientific programs. I am going to focus my discussion today on the scientific research funding. The first two boxes represent the intermural research program for which we provide millions of dollars in funding to FDA investigators studying sex and gender differences in women's health concerns. OWH has a robust program in which we fund research external to the agency through the centers of excellence and regulatory science and innovation and the broad agency announcement. Just to give you an idea of the types of research that OWH funds, on the top left you can see there's a pretty good distribution of funding over a wide variety of research topics and fields. And in terms of research focus, bottom right, even though we have no quotas in terms of the research we fund, it turns out there's pretty

much an equal distribution of funding among projects studying sex differences, pregnancy and lactation and conditioned solely or disproportionally affecting women. The ultimate goal of funding all of this research is to make an impact.

This shows research funded through our IM program. But I assure you that we do fund BAAs. In the last four years, we have funded several BAA. The two studies you see here are surveys. Behaviors related to medication, safety and use during pregnancy and determinant of hormone therapy knowledge.

The third study is a bio molecular bench science research focusing on predicting the transfer of medicines which are BCRP substrates into human. We are willing to fund all kinds of research from social behavioral science projects to bench science. Our research funding is on the road map available on this website. This first of its kind road map incorporated across agency input to help create strategic direction for womens health for the agency. Its purpose is to develop a strategy for determining the focus of future OWH research. And this road map is based on data from an analysis from our research portfolio.

In the road map, we identify 7 priority areas you can see here. Priorities are numbered but not in a specific order. No priority area is not important than any of the others. Here I'm showing a snapshot of the areas of research that OWH has funded over the last ten years.

Most common areas of research include cardiovascular, medical device, OBGYN and oncology. And there are some key areas of research missing including autoimmune diseases, cosmetics, dermatology and even the categories that look like they have a lot, still need more research on things like enDROE meet owe sis and fibroids. We're looking to fund more research using this as it pertains projects involving women's health.

Based on the information gathered through this process. OWH developed a list of priority research areas where new and enhanced research is considered essential to OWH and FDA's mission. Every year we create a list of our research priorities. These are the OWH research priority areas for FY24. Do not feel limited by the topics on this list. We will consider projects in which involve key women health issues, particularly those that have not received recent research funding. Aligned with the OWHs research road map priorities, include cross cutting and multi-disciplinary women's health priority areas important to the agency and threat across the centers.

Thank you so much for your time and attention.

>> Thank you for your presentation, Dr. Obidi. I would like to invite the panelist for this session to address the questions.

>> Hi, everyone! I'm the deputy director in the office of womens health and I'm happy to answer your questions. I can see one in the chat about intersex and yes, we're aware that there are intersex individuals but I wasn't sure if there was a specific question about womens health and intersex.

>> Do we have any additional questions regarding women's health? Please feel free to type in any additional questions and we can refer to our office of womens health and respond back to you regarding these questions. So I would like to request our AV team to put up a poll for questions, especially for non FDA attendees and we will leave the poll open for 10 minutes that comprises of a bathroom break as well as time to address this poll. At this time, we will stop recording this session and then start

recording once we come back with the presentations for the later half of this session. Please note these questions are especially for non FDA attendees.

The first question is, do you anticipate to submit an optional paper between November 6th, 2023. In the next session, we'll go over the details for the concept paper. The second question is, RS do you anticipate to submit a free standing concept paper or free standing full proposal on or before February 19th of 2024 and the last question for non FDA attendees, is your Sam registration up to date?

Thank you, we are back from the break. I would like to request our AV team to show the slides for the next presenter. Dr. Chada?

>> Dr. Kinnera Chada: Good afternoon. Everyone. I am the program lead for BAA. That is housed within the office of regulatory science and innovation ORSI and the BAA team oversees the logistics as well as the review related information for the BAA program. Next slide, please. So in the next few minutes, I will be going over the overview of the application process, provide updates for the application process, RG discuss the required templates as well as technical proposal which most of you know as volume 1 of the full proposal. Next slide, please. So as we have noted, the BAA application process was posted October 2nd. As part of the requirement process, it has been noted that all submissions require a free standing concept paper and free standing full proposal. So in this info graphic here, I would be going over how we use the concept paper and the full proposal in our review process. So once we receive the concept paper in February, we would be sending it or sharing it with the program leaders within FDA offices and centers that have provided scope for the FY2024 BAA solicitation and they will review the concept paper on the high level for program alignment as well as technical soundness. This is a basic high level evaluation. Based on the evaluation, there's one of the two out comes that you see in row two of this info graphic where it would either proceed to stage one or regret notification would be sent to the applicant. If it proceeds to stage one, the full proposal would be reviewed based on the evaluation criteria that has been specified in part four of the BAA solicitation.

The outcome for stage one would be one of these three which is shown in row 3 of this info graphic where either award could be made based on some clarification for the applicant or if there is a recommendation from the technical evaluation panel, saying additional revisions would be needed, then it would proceed to stage two where the applicant would be informed about the feedback from the panel as well as would be given 30 days to submit the revised proposal and then the third outcome, possible outcome is a regret notification after the technical panel evaluation.

Now, the outcomes for stage 2 would be based on review of the revised proposal by the same technical panel, most of the time and then the outcome would be a reward or regret notification. Next slide, please. So this table here shows the comparison of what would happen in the past review process for BAA station where it says the current process that we would be following. With the high level evaluation. In the past, this was reviewed by the program leaders for priority alignment with their program and also, funding priorities for technical feasibility of the proposed method.

For the upcoming BAA application, concept paper that would be submitted by the applicant would be reviewed by the program leaders for a high level evaluation. For stage one in the past, we would review the white paper and then an invite or a do

not invite notification would be sent to the offerors with the current process and the stage one, it's a full proposal that would be reviewed based on the evaluation criteria listed under part four of the BAA solicitation.

Stage II would be in the past, if you received a full proposal based on the invited letters or invite for a full proposal, we would review it with the technical panel that had reviewed the white paper but in the current process, it's the revised full proposal that would be reviewed as a part of the technical panel. This year we have also introduced an option for submitting an early concept paper. Please note that the option of the early concept paper is optional only and the outcome for the optional only concept paper is for FDA to provide a recommendation or provide a recommendation to or not submit stage one package during the February timeline.

The due date for optional early concept paper submission is November 6th of 2023. The same template is used for optional submission, either in November or the required free standing paper submission in February of 2024. Next slide, please. So once again, concept paper will be evaluated to conduct a high level review to determine the potential program alignment with FDA priorities and mission by the program leaders. Please see attachment 4 of the template and additional details regarding the early concept paper or the concept paper and these, the optional concept early concept paper is optional process only. If you would like to receive no recommendation for stage one packet submission in February, please submit an early concept paper.

The concept is overview and cover page or the method being proposed. Next slide, please.

So the concept of the page is listed here in the info graphic under the arrow. For the next few slides, I would be going over each of these required fields for data industry. We had multiple questions regarding the page limit for the cover page. Please note that the cover page as well as the overview is included in the three page limit. In total, the page limit is 3 pages. There's no restriction. The cover page is only one page or more than one page, or if the overview of the concept paper is limited to two pages. In total, the cover page as well as overview should be provided within three pages. Next slide, please. So the first requirement I'm going through is the charge area. Last area at the BAA day, charge area, regulatory science framework was presented by an office and this is what it refers to. Either charge one which is modernized development and evaluation of the FDA regulated products or charge two as well as charge three. This has been provided in table one of the BAA solicitation and also provided in text. So depending upon the scope to which the applicant is responding to, please he light or provide the charge area. And also, in the 1 p.m. presentation from various centers and offices, they had referred to some of these sections as 1A, 3, and so on and so forth. Next slide, please.

Now, with respect to the next data entry which is regulatory science topic area of interest. You would see under this area, there's research topics or regulatory science topics that have been referred to alphabets starting from A-K through charge one, A-G for charge two, and A-G for charge three. So depending on the scope to which the applicant is responding to, please provide the relevant regulatory science topic area of interest. Next slide, please.

With respect to FDA regulated areas, it is the product area which you would see in the table here indicated by the arrow. It would either be cross cutting, biologics

related, biosimilars, devices, drugs, tobacco products or feel free to add others if none of these fit the scope but as part of the station, you would be seeing specific scope under each of these FDA regulated areas so choosing an option of other, would be something that does not fit in these areas or scope requested. Next slide, please.

Want totem graphics and populations, we have list the scope of racial and ethnic minority, womens health related scope, persons with rare diseases have been listed as part of the scope and then oncology related topics would go to persons with cancer. Next slide, please. Next slide, please. So we have questions regarding how do you identify the codes for primary and secondary research areas so I have provided an example here from charge 3 and you have heard OCET priority listed under this for MCMI so I have provided a snapshot here on the right which is a condensed scope which has been provided in the FY24 BAA solicitation. Then you will see as part of the solicitation that if you are responding to a scope related to say the first column here, which is under charge three, under bullet number two, specifically for sublet three, then the research area, either primary or secondary would be listed as 3.A.2.C. You will see additional examples based on which one is the applicant submitting a concept paper for or a proposal for. Next slide, please.

So research development justification is a required field. Please report to Federal Acquisition Regulations for 35.001 and for various opportunities for research and development related contracts. That would be a required field for the cover page of the concept paper. Next slide, please.

The last data entry -- sorry, previous slide. Data industry for option early paper concept status is more to find information. If you have received a recommendation to submit a stage 1 package for February, after providing or submitting one in November, you would be provided with a BAA number. If possible, please provide the BAA number and primary research area in which a new submission has been made. Next slide, please. So the previous slides covered the required concepts or required data fields for the cover page of concept paper and then this slide would cover the required fields for the concept paper overview which comprises of research strategy that would include aims, methods and considerations. Please see the details attached to number four of the FY2024 BAA solicitation and regulatory science impact, what is your understanding of the regulatory science impact of this concept paper that you're proposing and then the proposed variables and funding. Next slide, please.

So the full proposal is also a required submission for February 16th due date and the full proposal expands on the information provided in the free standing concept paper. The full proposal must be prepared as two separate volumes similar to previous year's submissions. Volume one is technical proposal and its related appendixes and volume two is the cost proposal and any related appendix for the cost proposal. Next slide, please. So the template for volume 1, technical proposal has been provided as an attachment on attachment number 5 for the FY24 solicitation. I would like to bring your attention to some of the new required fields that have been added. Which is a number 6-8 that covers scientific and technical information, regulatory science impact and resources that help with the evaluation of your proposal. Also, please note as part of this statement of work is required and any additional information for related to intellectual property is also required to be included as part of the appendix so it does not cut into the required page limit for the volume one technical proposal. Next slide,

please.

So these are some of the due dates that I would like to get your attention to. Due date of November 6th, 2023 is for option early concept paper submission. Please note, once again, this is optional process only. And then the out come is to recommend or do not recommend stage one packet submission during the February 19th due date. If you have received a due not recommend stage one package and if option feedback was provided by the program leaders, that would be communicated to you and please feel free to submit a revised package statement during the February 19th due date.

January 12th, 2024 is the last day and then the outcome is basically to communicate updated funding priorities for FDA. These amendments would be posted biweekly every Friday and the dates for specific amendments have been included in the BAA solicitation. Please note, January 12th is the last day of posting any amendments for the BAA solicitation.

The other day to keep in mind is February 19th which is the stage one package submission that would comprise of free standing concept paper and a free standing full proposal package and the outcome would be, we would review these based on the two step process of high level evaluation of the concept paper and then if recommended for stage one review, technical panel would be reviewed in the full proposal and please note, that February 19th is the due date for consideration within the FY24 funding.

Applications after that would be considered late and would not be considered for FY24 funding but because the VA program is a rolling application basis, they would still be accepted and reviewed after the review process for the on time submissions to be completed. Next slide, please.

Thank you very much once again for your time. We will be taking the Q & A section after the next presentation. I would like to request AV team to pull up slides for Mr. Weiss.

>> Dr. Weiss: Good afternoon, everyone! I'm the branch chief for scientific support services. I work for Ms. Vidya Vish. I am here to talk about the type of contracting specific end of the outcome of all of these BAA, so many of the folks on the line and online there, have done business with FDA before, many have not. The we're going to talking about the contract specific pieces of this, talk about the difference between contracts and grants and then as said, get into the question and answer session for the many questions that have come in that speak to these contractual issues so next slide, please. So what is the purpose of this day? It's to take advantage of the virtual event and opportunities provided so that we can, you can hear a little bit more from the different centers, meet some of them, virtually meet the program folks and that worked with the attending FDA staff to include myself. L you have heard several times what the purpose of the broad agency announcement is so we're not going to bore you that again. Next slide, please.

This is a big one you heard, several of the program folks talk about this. What is a difference between a contract and a grant? I have been sitting in this chair, oh, a little over a year now. And I definitely have seen that there is a bit of misunderstanding with our industry and educational institution partners as to what is a grant and what is a contract and to be absolutely clear and I know it's been brought up

several times within today's presentations, but the outcome of a successful BAA proposal is a contract with the federal government specifically with the FDA. And what does that mean? What are the differences, right? The government uses grants and cooperative agreements as a means of assisting researchers in developing research for the public good, right?

A contract is a means of procuring a service for the benefit of the government. Now, often that also means, there is public benefit obviously but specifically, it is procuring a service or a good and most of these cases, it's a service. Grants are much more flexible than contracts. Typically with federal contracts, changes are not made easily through the scope of work or budget specifically where as in grants, changes are usually made with minimal approval. The big one is failure to deliver the agreeable tasks can have potential negative consequences. The case of a grant, typically the final report explaining the outcome is efficient. So to expound on that, with some bullet points, the difference between the two.

The grant is a flexibility instrument designed to provide money to support a public purpose and they can be very flexible. They are flexible as to the scope of work. Budget and other changes. Diligent effort are used to do this, best effort in the delivery of results, payments usually awarded in an annual lump sum. There's really a minimum, annual reporting requirement and then this is a big one.

The principle investigator has more freedom to adapt the project and less responsibility to produce results. For a contract, which is again, you'll hear me drive this home during my presentation, a contract is a binding agreement, between the buyer or seller, or a vendor and an educational institution, in returns for consideration and in the case of the federal government which is usually money. It is governed by the federal acquisition, regulation, so to be fair, it's relatively inflexible as to change the scope of work, budget and other types of changes. Significant emphasis is placed on the delivery of results, generally in the case of the BAA not product but performance. Payments are usually based on deliverables or milestones except in the case of a cost reimbursement contract. Often there's frequent reporting requirements and then a high level of responsibility to the sponsor for the conduct of the project and results. Over the past year, as I have gotten really, in trench with the BAA program, I have come find there are folks that misunderstand the differences between the two. So when we're talking about, you know, we use the term a BAA. The BAA is just a process to get to a contract. Once the contract is awarded, it's a government contract and we administer it in all of the same ways we administer any other contracts. Next slide, please. What is new for the FY24 FDA BAA from the contracting perspective? Again, she went over the significant changes to the submission process, why the change? While BAA days are relatively new, the BAA program has been around for over a decade now.

What we're looking to do is change the process to reduce administrative burden on both folks putting in proposals and reviewers and allowing for contracts to be issued earlier in the fiscal year for those who are awarded contracts or have contracts with the federal government, and currently you know how there can be a crush of contracts at the end of the year and we want to allow for, you know, meaningful negotiations and better contracts to be written. So we're trying to free up some time earlier in the year to be able to do that. And hopefully we'll see some positive changes, both for the submitters and for the government side by implementing these changes.

Next slide, please. We will talk a little bit about severability and not severable. Severable describes and you'll see it in the BAA announcement where we talk about preference to a severable, two or more parts not necessarily dependent on each other. Non severable describes an action that cannot be separated without negatively affecting the performance or task. IE, we will say it's a three stage research project. At the end of stage one, is that a point where if things are not going the way we thought it would, is that a point where we can sever the contract and say, it doesn't look like we can support stage two and go from there?

When you're building out your proposals, give some thought, can we make it severable or not? If it makes scientific sense to do that and we, you know, on the contractual side, we have a preference for some severable services that make it so you're not, again, this is a contract with firm deliverables so we don't want to put any of the vendors or institution ins a position where they need to keep working on something they don't think is going to work out and we don't necessarily want to pay for something that maybe is not going to go the way that everybody thought. So just give some thought for severable versus non severability in your proposals. Next slide, please.

This is something that came up quite a bit in the past year, can we expect negotiations to be part of the contract award process? My answer to that is, we always reserve the right to negotiate with each offeror. And it depends on a lot of things but negotiations are always possible. There's just a ton of variables and to be transparent, about 50% of the contracts that we issue for off of last year BAA required some level of negotiations so what I would say is, yes, we can expect both your research team or principle investigators and your contracting folks to need to engage in some level of negotiations prior to awarding the contract. So how can you improve your chances if you're not selected this year?

As you saw, the different stages, you will be given feedback here or there and while they vary in reasoning from incomplete packages to limitations and funding, which are petty self-evident, relevance to the research areas and so on, you can always request to speak directly to the CO, that would be me and if you're looking for more specific feedback, if that exists. And I'm always happy to talk to you and tell you to give advice on how you're going to do, put forth more targeted proposal next time. Strictly from a contractual standpoint. Another issue that we have that I would like to point out to everybody, again, some of the smaller vendors and institutions are new to Sam.gov. Sam.gov registrations can take a long time. They used to be able to be done in a matter of weeks. We're finding now that some folks are backed up, three, and four months. Sometimes longer. I just want to point out, again, this is a contract, not a grant. I am legally restricted, pardon me, not able to give unto someone who is not registered in Sam.gov. Please make sure, absolutely take time to issue the contract, and be entity, needs to be fully registered for all awards in Sam.gov. I would highly recommend that as you're building your proposal, if you're not sure as to your status in Sam.gov, that you know, when you're building your proposal, or right around when you submit your proposal is when you should be checking that. Unfortunately, we had a couple of entities that we would have liked to have given contracts to, that we were unable to because their Sam registration was not finalized by the time the fiscal year ended. We really hate to see folks in that position. We would like to pay them for a service that seems valuable but we couldn't because of a registration error. So that

was the purpose of the polling question and the purpose of me bringing it up now. It's not a terrible amount of work. It just can take time and the FDA does not own that process. So I highly recommend that you, if you have contract folks, that they double check it sooner rather than later.

So what if you're new to this process or a small business? You're in the right place! This is the time to do that. And also, I want to use this as a small business but I want to use this as an opportunity to plug the fiscal year FYs 24, FDA small business fair that is going to be taking place Wednesday, November 15th. That is from 9-4, both virtual and in person at the FDA White Oak campus. So we will have multiple FDA sponsors there, multiple FDA contracting officers there to include myself. I'm happy to talk to any vendor that comes about, you know, contracting with the government in general or if you have specific BAA contracting questions, I'm happy to do that. Again, it's both virtual and in person. You can go to Sam.gov to search for Food and Drug Administration, small business fair, fiscal year 2024. I will drop a link in the chat. In addition to being here today, for today's BAA presentation, I would highly encourage that you attend the small business fair and there will be a large business there if you're looking to partner or looking for subcontracting opportunities and any of that kind of a thing. There's going to be large business partners there as well so I would highly encourage attendance, either in person or virtually. I will drop a link in the chat.

If you have questions and it's from a research perspective, these are the folks to speak to if you have contracting question, come to me and we can get you what you need. So what am I prohibited from doing? I cannot review the proposal before the submission, answering what should I research, what are my chances kind of questions. And I have already seen a couple pop up. What are other people submitting? I can't answer any of these things and I will just put it out there now because we had a couple of questions pop up in the questions and answers.

Generally we don't talk about current budgets. To be perfectly fair, year to year, we don't necessarily know where the budget for the BA program is going to be, especially this year, if anyone has been following the news, the federal government in general has some challenges right now with regards to what the funding levels are going to be for the rest of the year and we would really be remiss in trying to read the tea leaves and give folks any kind of expectation as to what this year's budget is going to be. If you have interest in last year's results, if you go to last year's BAA posting or you can search FY23, FDA, BAA with the award notice, we awarded about 4-6 million dollars, I believe, 40 awardees in total. So this is generally what we award. Again, this is just the historical trend with no guarantee we will do it as a minimum or a maximum.

This fiscal year, that was a significant drop in funding from the previous year but as noted by a few presentations up until the end of last fiscal year, we had access to some very specific COVID-19 funding which is no longer available to anyone in the government. And so, again, you can look at that. You can go back several years on Sam.gov and see the award notices and the trends. It's generally, you know, 4-6. Last year it was 4-6 million dollars somewhere, generally, 40 to 50 awards and as far as what this year's budget is going to be, we really can't -- we can't disclose anything because frankly we don't know anything. That's that. May I have the next slide, please? All right. So I guess we will get right into the question and answer section. I

think we have some. So I know we have some in the questions and answers here in the Zoom chat but I think, that we have some that are kind of present to us and I think that was where we will start if I'm not mistaken.

>> Thank you, Ian. Yes, we received a few questions from the BAA inbox and this first question is directed to you. Table three overview of the BAA application process on page 96 of the agency announcement indicates that the FDA will notify submitters of the optional early concept paper of the interest or lack of interest for full proposal submissions. Does the FDA have a target date or date range in mind for sending these notifications out?

>> Yes, I think I was looking at somewhere in the neighborhood of the middle of **November 15th** of **November** However, just as I mentioned, we're not sure what is going on with our friends in Congress. And so if there's a lapse in appropriations, I would ask that everyone bares with us because not everyone here will be necessarily working during any lapse of appropriations so that is our goal to have it out, beginning the **15th of November** so there's a potential lapse of appropriations on the 17th and that could dramatically impact that. We will endeavor to get it out as soon as we can but no guarantees. It's unfortunately not up to us.

>> Thank you, Ian. The next question is directed to Kinnera. Is the concept paper limited to three pages with single margins, inch, font size 12?

>> Yes, that's correct. That includes this based on the instructions provided for the FYs 24BAA solicitation that Jessica just read.

>> Thank you, Kinnera. The next question is for Ian. Will funding be available for phase one, two or three clinical trials and whether the BAA fund the development of surrogate endpoints that can be used as the basis for regulatory approval?

>> Ian: So, as is the case with many contracting questions, it depends. We are capable of phasing one through three. It depends on your proposal whether or not there's interest in funding all or any of the different stages. That said, the one thing we are prohibited from funding is anything to deal with the actual regulatory approval process so it gets a little dicey, you know, when something is being prepared to be used for regulatory approval. I think that's kind depending on the proposal and contracts but any direct associated cost and fees to deal with the regulatory submission and the regulatory approval process would not be funded.

>> The next question is for Kinnera. If we have several distinct ideas, would you prefer we combine them to one, three page concept paper or submit them as a separate proposal?

>> If they are distinct ideas, please submit them as separate concept papers.

>> Thank you, Kinnera! The next question is to Ian. Is there limitations on the size of the award?

>> No, there's no limitation on the size of award. Again, I would caution folks to look at historical dollar values. All of that is public. Generally speaking, most awards are 2 million dollars and under. But those, that follows the different proposals that came in. That doesn't mean that a 10 or 12 or 20 million dollar would not be funded but just know, there is a finite pool of money and we don't know what size that pool of money will be this year. But no, there's no restriction on you putting in a 50 million dollar proposal. Is that realistic? I don't know, but you're certainly not restricted from doing so.

>> Thank you, Ian. The next question is for you as well. Ian, can we discuss the impact of paper work reduction act or proposals?

>> Ian: Absolutely! Many of the BAA contracts that are awarded are impacted by the paper work reduction act process or PRA. What I would like to caution everyone and this is both for, I have spoken at length to many of the program folks and some of the contract partners as well. What I would like to caution folks on is, we as a group, as a collective, tend to be a little overly confident in our ability to maybe get a waiver. So proposals will come in and you know, folks will budget a month or two for the PRA process. And I can tell you from practical experience, that's generally not the case.

In fact in the last year, I haven't seen a waiver granted yet and I would caution folks, when you're building out your proposals, if you think the PRA process is going to apply to you, the PRA website states it's a 9-12 month process and I would probably budget that kind of time certainly if we get lucky and a waiver is put in and the waiver is approved, you know, we'll happily adjust periods of performance and all of that kind of a thing. But I would probably caution everyone to plan on the standard PRA length of time for the process.

>> Thank you, Ian. The next question is it accessible and recorded?

>> Yes, it will be recorded and is accessible. That's it from the questions for the BAA inbox. I'm going to look through the Q & A.

>> I can grab the first one if you would like. First question is, are co investigators allowed on the application? Absolutely! That's a business decision by the folks, whether it's an educational institution or a commercial vendor. That is your business decision as to whether you have one or multiple principle investigators.

Two things I would caution. One, the government prefers to have a single point of contact for those kinds of things, so whether you want everything to go through your contracts person or one of the principle investigators, I recommend a primary point of contact is very much preferred. And then also, and I know I might be getting ahead of myself a little bit here, but are they a part of the same organization or is this, like, has your commercial entity or your educational institution partnered with some other entity to bring on the co principle investigator? Completely fine. Again, this is a business process on your part, pardon me, a business decision on your part but that would then get into the possibility of subcontracting and if you're a large business, a large entity, that gets into you needing to make sure you're a subcontracting plan is updated, you also need to make sure that the prime vendor, whether educational institution or commercial entity is performing 51% of the work. So yes, you absolutely can bring on more than one principle investigator but just remember the asterisk there, is it going to impact subcontracting and make sure you provide the POC to the government. We talked about this one too, we already talked about it. If you want more details, we have already discussed, go ahead and check the award notice from last year, or the year before. They are all up there on Sam.

That was mine too, data sharing or publication requirements? Generally speaking, the government has limited data rights to the outcomes and deliverables that come from this. There are generally requirements for data sharing or publication with regards to the government being able to make certain things public. If you have questions about whether or not your organization can use this data for other projects or publish it can and all of that, it can be discussed at the time of negotiations for the

government and generally speaking, from my experience, the FDA looks pretty favorably on educational institutions looking to publish information to make it public. In general, yes, but don't assume and let's discuss it with negotiations.

How many applications are anticipated for this round of funding? We don't know. I think last year from the white paper perspective, Kinnera, we got like 280, right?

>> Kinnera: Yes, close.

>> Ian: And then full proposals, 80 or 90?

>> Kinnera: Yes, that's right.

>> Ian: So I really can't answer. I would love to give you an answer and we would like to know too, but ultimately it's up to how many folks decide to put in a proposal and ultimately those numbers are made public I but I can't give you an answer now, unfortunately. We can dismiss that one.

So I'm at a University facility for AI and machine learning to apply for an FDA grant. Contracts, we're talking about contracts. I can't really speak to grants. Do I have to partner with the medical doctor or someone within the FDA? No, not necessarily. You put in a proposal and again, as your business proposal, your research proposal, it will stand on its own merits and if you feel that partnering with a medical doctor, is in your best interest to submit, based on whatever you're researching, we encourage you to do that but it's certainly not a requirement. And if a contract is awarded, there's a technical sponsor that can help you navigate those things.

Okay, based on the feedback received last year, our proposal was scientifically sound but had question on regulatory -- can we resubmit the enhanced proposal this year addressing the concerns? I think from a contractual standpoint, yes. Kinnera, I would say, would you agree that as long as it is in alignment with this year's research areas of interest?

>> Uh-huh, that's right!

>> So you know, if it falls in it, if it falls within that, I would say yes. If it doesn't, it needs to stand on its own merits and I don't know if you would have great shot with that.

>> You can also consider doing the option early concept paper to see if it's a part of the high evaluation from the program leaders, if it would fit with the program alignment or technical merit. They could get a recommendation to or not submit it.

>> Additionally, can we reference the concept in the revised concept paper? Absolutely. You decide what to put in there. So if you feel it's valuable, you know, you understood the concerns and you want to point out how you have addressed them, absolutely, put it in there but it's your decision. Typically size of award and funding, we discussed that. Would technology that shows lower cost be of interest? Contractually, sure? The government loves to save money but Kinnera, do you have a better pulse on how that might be looked at?

>> Kinnera: I think that's a question that would be deferred to MCMI or grants manufacturing because that's a question received for that session. I would have to check and get back.

>> So maybe a good answer is, if you have those kinds of questions, it would be very valuable to put in that optional concept paper because that way you can get your question answered without the effort and expense of putting together a full proposal. All right.

>> So regarding the next two questions, we would have to check with the center for excellence, oncology, as well as office of womens health and center for tobacco products and respond back to the applicants or the questions that has been asked.

>> This is a joint answer. There were multiple reasons to change your process for full proposal. As Kinnera showed in her presentation, there is still a screening, kind of a prescreening, stage one, stage two screening process. We definitely had a discussion. We may get more full proposals than normal but ultimately, it's still two stage review process but what we were trying to attempt is to get, you know, more of a streamline approach for both industry and government. So that is a reason for that. Anything to add to that one?

>> No. The you've covered it, thanks!

>> I think regarding this question for pregnant women, we would have to check with the office of womens health and respond to you. Let me check to see if we have a panelist still available to answer this question. We do not. We will get back to you regarding this.

>> Yea, and just, as a reminder to everybody, all of the questions and answers are put on Sam.gov and all of the one offs we can't answer live in session, we can formulate an answer and publish it so everyone can see it. Do international submitters need a Sam registration? Yes, you do! It's even more complicated than some folks internal to the U.S. so there's a whole state department website devoted to what you need to do, if you're international and you want a Sam registration, I would highly suggest if you're international and you think you might want to put in a full proposal for award, that may be something you look at sooner rather than later. That could be a lengthy process for international folks.

We still have a BAA submission from 2023 that was not awarded or rejected. Should we wait in.

>> We have already addressed this question.

>> If the U.S. government shuts down, does it effect your timeline? Yes, it will. How it affects the timelines depends on how long it's shut down. We will be very judicious in being, posting updated timelines as soon as we can. The I will say, regardless of the shut down and be here. I will still be able to post some things to Sam.gov, keeping folks updated to the changes in timelines and all of that as we can. It really all depends, if we shut down and for how long. If it's for a few days, it shouldn't impact anything. If it's anything like the 2018, or 2019 shut down, we will probably have to retool the timeline considerably. We will make that public and make those decisions as quickly as possible as soon as everyone is back and able to put that out there.

I thought the concept paper is optional. Can you clarify for us? Thank you.

>> So the concept paper that is optional is, if you are submitting an option of early concept paper on or before November 6th of 2023, after that date, any submission for BAA would require applicants to submit a free standing concept paper and a free standing full proposal. The benefit of optional concept paper, early conception paper submission, on or before November 6th is to receive a recommendation for stage one packet submission or not submitting the stage one package, on or before February 19th. This is more catered towards small businesses so they can invest their resources for a full proposal submission based on FDA's priority. Any submission after

November 6th, would need the concept paper as well as full proposal to be submitted for consideration for the BAA FY24 review process. The optional concept paper is only optional and not an invite or do not invite recommendation. It is only a recommendation for submission or not submission for stage one package.

>> How much feedback is provided about decisions for concept paper, or ways to better focus proposals for future submissions? That really depends on the program leaders that are reviewing the concept papers. We have some programs that are interested in providing a detailed optional feedback that is communicated via our acquisition office to the applicant. There are some programs that would like to provide minimum feedback regarding if they would recommend a stage one package submission for February or they do not recommend. L so it really depends on how much feedback you receive from the program leaders. Do you want to take this question again? The next question? That was a slide for my presentation, related to optional, early concept paper submission, that you receive November 6th.

>> We had to discuss this earlier. Optimally, we're getting it out some time mid November but it will depend on whether or not we shut down.

There was one slide that says, whether we -- I do not understand this comment in the optional context paper.

>> So for optional concept paper, it's not an invite or do not invite. It's only the recommendation from FDA to submit a complete stage one package for February 19, 2024. This is a process we are introducing to check to see for the applicants regarding FDA's priority interest in reviewing or receiving full submission in February for that specific topic.

>> Can applicants of one proposal come from two different organizations, like two different Universities, through which to submit the proposal? That's completely a business decision on your end. You can partner however you would like. If you're a commercial entity and you want to make a joint venture or, you know, you're in the property jay mentoring program, do that. If it's two Universities that want to get together, business process as to which one submits. It's really up to you. Totally acceptable to have some kind of joint venture.

Are the contracts cost sharing? Generally not. I think I have seen a few when I went back and looked at historical but the last two or three years, I haven't seen any cost sharing generally. Do you recall any? Generally not. You can propose it. That's your proposal. As a compelling argument as to do that, we would like to hear it. It's not a no but generally. Oh, boy!

This is a toughy. From your experience, please provide practical hints, critical points to focus on, common deficiencies in applications and what should be avoided, what to take care of particularly? I would say number one include all of the applicable required items. That was probably the biggest thing last year. Incomplete packages. We have some proposals that didn't align well with the research areas of interest. That is a good way to get knocked out.

>> Make sure the proposed ideas cover one of these areas under research and development for BAA contract.

>> We can probably spend an hour talking about all of these things. I would say the big ones, your business development people, contract people, whoever it is, that reviews your proposals, make sure they review it against their requires of what is asked

for in the BAA posting because that's the easiest way to get it knocked out.

Have all of awards been made for BAA for FY23? All of the FY23 awards have been made. As Kinnera has mentioned, there's still a rolling process to where if funding becomes available, and there's additional contracts awarded with FY24 funds off of the FY23. I know at least one that has happened. So the answer is, maybe. Do you want to take this one?

>> So this are mostly for public to use. If they are in the agency, it wouldn't be under the regulatory aspect or fee based. That's the significance. This next question that we have posted on the Q & A session has to be checked with our OCET office and we'll respond back to you. Do you want to take this?

>> Yes, I'm responding to them directly. So what is the typical period of performance or range of contract value? We talked about contract value. There isn't a typical period of performance. We have proposals that only run for a year. We have some that run for five. And we have everything in between. So while we have the ability to go beyond five years, I can tell you especially here in the FDA, it's pretty uncommon. I would be hesitant to propose something that would run more than five years. Anything between there, we can award any of those five years.

>> I answer this in general, what does it mean remote monitors? To replace on site inspections or compliment them and the answer is yes. In some cases, it is to replace on site inspections completely and other areas, it may just be to compliment them or cut down on the number of on site inspections. It's really dependent on the contract and that's the kind of thing that, you know, if you get to the point where we're getting, you know, looking at awarding a contract, that is something you should bring up in negotiations so if you have concerns as to you, would prefer so many inspections or virtual, any of these things, it's something I would bring up in your proposal or if you get to negotiations, bring it up in your negotiations to define this for you.

Who is a formal applicant -- in case of researcher or University, generally speaking, it's the University. And then the researcher would be the principle investigator. You're more than welcome to register as a Sam entity on your own. Generally speaking, we haven't seen any individual researchers. It's generally, you know, some kind of commercial entity or educational institution. Oh, we have answered that one. I think.

What is the recommended way of getting in touch with you? So for anything regarding the BAA, I can't more lily recommend everything going to the BAA inbox. If you go to Sam.gov, it's in the submittal. The if you have general contracting questions, my e-mail address is up there and I'm happy to answer general contracting questions but if it's targeted BAA question, it's best to go through the BAA inbox. Also, I forgot to mention this during my presentation so this is a good place to plug it in there. When you're submitting your proposals, and your optional concept papers, please make sure that you're sending them to the BAA inbox. Some of you will sometimes send it directly to me or one of my specialists that maybe you have dealt with before or maybe to, you know, program folks that you have dealt with before. And if it doesn't go to the BAA inbox, it will not be reviewed so make sure you're sending it to that. And one other related thing, as far as timeliness, I want to put it out there and it will be clarified a little bit better in the next amendment to the BAA posting but late is late. We had some folks, it's only an hour or two or day or two, late is late. We have a specific date and

time everything is due. When that time and date has passed, it's passed and it's late. So we're setting the expectation for everybody.

All right? Who can apply? Small business, academia, small business plus academia, yes! We welcome and encourage everyone to apply and whatever way it makes sense from a business perspective, and a research perspective, it makes sense for you to apply that way, apply that way. Really, again, that entity awarded the contract, needs to be one properly registered in Sam is really the only restriction.

>> This is probably better for you, Kinnera.

>> For the cross cutting section of the chart, which office center do we know to write to?

>> Sure, thanks! So once we receive the concept paper in the cross cutting section, it will be shared with the appropriate program leaders, pretty much all of the program leaders will review the cross cutting section to see if the concept paper would align with the priority. So there's no need to specify the office or receptor. Please send your questions for clarification to FDA inbox listed in this solicitation and as part of the concept paper cover page, please use cross cutting as your choice. Is the two million guidance over the course of multiple years? I was saying, total contract value. Again, it's -- you know, your proposal stands on its own merits. Again, there has been a year where we awarded multiple items and be this is a lean year, maybe one or two over five million dollars. So let your proposal stand on its own. If it makes sense, at whatever dollar value, we don't want dollar value to be a restriction but we are trying to say, be realistic in what we have available to give to folks.

>> Are there limits on direct or indirect costs in again, it depends on what you're proposing and what you're proposing it for. There's not necessarily a hard limit but definitely, there will come a point at a certain percentage level where we will ask you to justify those things and perhaps, provide other than, if it's a firm fixed price contract, we might ask you to provide, other than certified cost and pricing data. If we're looking at a cost type contract, we want to see how you can justify these numbers. So either limits, not necessarily. But know, you can and likely will be asked to justify those numbers.

>> I would like to request you to take the next question.

>> If the concept letter asks for a high level budget in total, be it's submitted in November, how much discretion do we have to modify the final discretion in February?

>> All of the decision in the world. If you choose to modify it based on the feedback, I would point out, we were given it and this is how we modify it but you have all of the discretion to modify that.

>> I would like to just add something to this, Ian. Just a note that the optional early concept paper is just for the applicant to know if that is a priority area for them to consider submission in February. That does not mandate any commitment from the applicant for submission in February or does not allow them to not submit, if they receive, do not submit recommendation either. This is completely optional.

It's completely optional. Is it a good idea? Probably. It's going to be reviewed regardless and just as the flip side to that too, just because you get a bunch of positive feedback on your concept paper, does not necessarily indicate whether your proposal will be accepted, you know. It may be too expensive or deficient or lacking in details. The all kinds of reasons but just be aware that's also the case.

>> I can take the next question. Please note, this is incorrect. If they do not submit the early concept paper by November 6th, that does not exclude them from submitting the full proposal in February. Please note that optional early concept paper due date, of November 6th is only optional. The outcome of that process is that you would be receiving a recommendation to either submit or not submit a stage one package. That does not confine the applicant to make a submission of stage one package or not submitting it depending upon what recommendation has been received from FDA.

>> What do we mean performing 50% of the work, sub versus prime? If you're partnering with another institution or commercial vendor to commercial vendor, whatever it is, one entity needs to be designated as the prime contractor. That entity needs to perform 50% of the work and that's across the board, federal requirement. So I don't know if that necessarily answers the question but that's needing, as an example, and I'm just making this up but it's not something that happened.

If we have a commercial entity that proposed we're going to study widgets this year and we simply hire a principle investigator as a sub contractor that does all of the work and the main contractor, the prime contractor just simply submits the results, you have not performed 51% of the work. That's the extreme example but that's what we're discussing there. The you actually need to -- it can't be just administrative in nature.

If the work does a research study, your folks should be the ones primarily performing those functions or 51% of the functions, just be aware of that.

Does this come into play when making award decisions, is any of this set aside for the small business? This is a very rare case. I will say that the FDA in particular, I have worked for a number of organizations. We take small business set asides very carefully here. I fully support it. For the BAA process because this is all about innovation and specialized research, for this, there's no small business set asides. Nor does the business size come into play. To be fair, the only time it comes up if there's two very close or identical proposals which to my knowledge has never happened. Everyone is putting their proposals based on their interpretation of a problem and a solution as they perceive it. So every other contract that the FDA issues, R absolutely! Small business, we set a lot of things aside for small business as we should. Absolutely, it's a factor of our acquisition planning process. Specifically, for the BAA program? No. It's not necessarily a factor.

>> Can a system integrator outside of the organization be used? Yes, it just gets into this subcontracting. Piece that we talked about. Minimum? There's not really a minimum amount. What is the minimum amount you can award through BAA? I haven't seen it. Do you recall any below this threshold?

>> I don't recall. You can award any value, there's no minimum. Generally speaking, it's above the simplified acquisition framework generally.

Are you more or less likely to receive funding if you recently received funding on a prior BAA? That's a joint question from a contracting perspective. I'm come completely agnostic on it. It's not a factor for my side of the table. Kinnera, do your programs work on that?

>> No, I don't think so.

>> Yeah, it's really based on the research and the scientific relevance. Does the

Sam registration have to be complete at the time of early concept paper submission? No. And it doesn't have to be complete at the time of full proposal. I highly recommend it's complete at the time of full proposal but to be absolutely clear, that does not prevent us from, if your proposal is selected for stage one, stage two, all of that, it's not going to prevent any of that from moving forward. Just as a, you know, having done the contracting things, the sooner you address it, the better. It only prevents you from the award if you get that far.

Would you recommend them to request a Sam number if they don't have one? In the case of subcontracting, it's not. It's not required. Again, that's a business decision but there's no requirement for the subcontracts to be registered in Sam.

>> Can the purchase of equipment be included for a justification in the cost? Maybe, possibly. We have legal ways of doing that. It really, I think would be based on the proposal and how does that tie into that scientific relevance and whether those centers agree to that but, there's mechanisms to do it.

>> Please provide the details for the small business fair. Let me grab that. That's the award one. I thought I put it in another one.

>> Also, the slides would be available on this page.

>> Please provide us details for small business info, I'm putting the link for that. It has all of the registration, times, dates, addresses and all of that good stuff. It's a hybrid event. We would love to see you there in person. If you can make it, if not, you know, we'll be happy to chat online as well.

>> This next question regarding the proof of concept. For the concept paper, I think the proof of principle based on published data is enough. Once it gets to the proposal and the technical panel reviews, it depends upon its is up to the technical panel to answer that question. But for the concept paper, proof of principle established data is enough.

>> Do OCC, other correct cost, does it account for the 51%? Generally no. It's the actual work direct. In the case of all of this from a contractual standpoint, this is all generally speaking, are service type contracts, right? So ODC does not count as general labor. And oh my goodness, I think we got through all of the questions.

>> Are references included? Yes, that would be required but, the list can be a smaller from what is required.

>> Are you talking about the table one as part of the presentation on my slides? If yes, that should be available as table one. In the BAA source solicitation that has been posted. That is the updated table we have.

>> Okay, and then we will be posting, I don't think this impacts any of the optional concept. Any of the optional concept paper but if we didn't mention it, we plan on posting an amendment to the BAA posting probably Friday, late afternoon. I don't it impacts that.

>> It's just formatting changes and questions we received.

>> Can the budget be submitted as options? Option periods and or optional items. We love options, options are good!

In fact, I would say if you know items that can be the numbers of people or things we can do, it's better if we do it but we can live about it and if they were submitted as optional items, that will be looked on unfavorably. I would say.

>> So I just wanted to reiterate, the optional due date of November 6th is really optional. There's no mandate for the applicant to submit that optional concept paper but however, if you would like to receive the recommendation from FDA to see how the concept paper or the proposal aligns with FDA's priority, we would like to request and encourage you to do so.

Irrespective of your submission on or before November 6th, that would not affect your submission in any way for February due date. For February 19, 2024, it is required that applicants submit a free standing concept paper and also a full proposal. If you have submitted an optional concept paper in November and you have submitted it, you will also receive a BAA number. Please use the BAA number to submit your stage one package. So if we do not have any additional questions, I think we can end this session.

Once again, feel free to send any additional questions or follow up questions to FDA, BAA @. When I post this amendment on Friday, I will go ahead and put a link in the description as the international Sam instructions so you can see, the folks that need it, can just follow and follow the state department instructions on that.

>> Once again, please note that the recording of the full event included closed captioning and audio transcript, presentation slides, responses to the polls and answers to all questions we have received e-mailed, and as well as Q & A will be posted on FDA's BAA event page. This is the same event page that was used for registering for this session.

Thank you once again for your time and we really look forward to reviewing your applications. Any closing comments?

>> Thanks, everybody! Yes, we look forward to concept papers and proposals and again, if you have one last plug for small business day, please try to attend if you can. There will be large businesses there so don't be scared away if you're a larger, educational institution. If you have questions, you're going to have a room full of program folks and contracting officers and specialists in the room. So we'll make time for you! ' Thank you so much to the AV support team for making this event possible and issue free.

>> Thank you, everyone!

>> Thank you, have a nice evening. Bye bye!