FDA Final Hiring and Retention Assessment
Public Meeting – March 15, 2022
Transcript

Yashika Rahaman:

Hello! Good morning and thank you all for joining us today for our public meeting on FDA's Final Hiring and Retention Assessment. My name is Yashika Rahaman. I am the Director for the Office of Planning, Evaluation, and Risk Management, under which this Final assessment contract was managed. Today I will be serving as the moderator for this meeting.

For today's agenda, I will begin with a brief background on the assessment, then we will have two formal presentations prepared for you. The first is from Kristen Stanton and Dena Papazoglou from Booz Allen's Talent Transformation team. They will provide an overview of their assessment results and recommendations. The second presentation will be from Melanie Keller, the Director for the Office of Talent Solutions who will present FDAs' Response to the Final Assessment. Following Melanie's presentation, we will make the chat feature available for any questions or comments from the audience.

As a quick overview of why we are all here today, FDA is authorized to collect user fees from sponsors and applicants to help expedite the development, review, and approval processes of human drugs and biologics. As a part of PDUFA VI and BsUFA II agreements, FDA committed to a series of three assessments of the efficiency and effectiveness of its recruiting, hiring, and retention of the human drug and biologics review program staff. FDA contracted with Booz Allen as a third-party evaluator to conduct the Interim and Final Assessments. I will now turn it over to Kristen and Dena from Booz Allen for the Final Assessment presentation.

Kristen Stanton:

Thank you, Yashika. Good morning, everyone. My name is Kristen Stanton, and I have been the Booz Allen project manager for both the Interim and the Final Assessments.

Dena Papazoglou:

And I am Dena Papazoglou, and I've been the technical lead for both assessments as well. Kristen and I both have extensive backgrounds in Talent Transformation, Organizational Excellence, and Human Capital, and together we will provide you with some general background information and key takeaways from the Final Assessment, followed by a detailed summary of the results and recommendations.

Kristen Stanton:

So, to set the stage, there are a number of factors that impact the recruiting, hiring, and retention of FDA's talent. While these are not all necessarily unique to FDA, they do provide context around ongoing challenges as well as emergent influences. So, for example, as a nation, we are currently experiencing an extremely dynamic labor market, which continues to impact the competition for high-value talent. There are also complexities related to simultaneously administering numerous hiring and pay authorities. So, while they do offer considerable flexibility, some have unclear or prescriptive requirements that are controlled at the HHS-level. In looking at the impact of COVID-19, FDA's HR workforce responded with an "all hands-on deck" approach and quickly transformed its workforce patterns and HR

service delivery. Job seekers also began to have altered perceptions and expectations around the [INAUDIBLE 03:51-04:16][1]

AV Support:

Hi, Kristen this is AV support. I lost your audio for a quick second here.

Kristen Stanton:

So, in hearing about the study's results, we believe that it's important for you to have a high understanding of the various staff who perform HR work at FDA and the HR Service Recipients. So, FDA's HR Workforce includes HR staff that are aligned to the Office of Talent Solutions, or OTS, and the Office of Human Capital Management, or OHCM. You can see [INAUDIBLE 04:40-05:00][2]

Dena Papazoglou:

Kristen, your audio… I think your audio has gone out.

AV Support:

Kristen this is AV support. Your audio is going in and out. Can you hear us?

Kristen Stanton:

Oh, does my audio keep going out?

AV Support:

Yes, it's intermittent. we can hear you now.

Kristen Stanton:

Okay, I did not do anything. Is it okay to continue?

Dena Papazoglou and AV Support:

Yes.

Kristen Stanton:

Okay, alright, just chime in if it continues to be an issue and I'll try the headset.

So, in addition to these liaisons that are in the Centers' Office of Management, the staff in the Centers' program offices, there are also staff there who perform administrative HR duties in addition to other program support. You can see these staff in the center of the screen. As the Center staff performing HR work are not centrally managed and so the official HR organization on the left has limited power and influence as it pertains to standardizing and coordinating HR work across the broader HR workforce. From a "customer" perspective, the HR Service Recipients shown on the right side are simply looking for efficient and effective

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[1] From the script: "…nature of work and employee value proposition, such as telework and wellbeing. And lastly, the Agency faces the risk of higher turnover due to the large number of staff (including many senior leaders) eligible for retirement, as well as employee desire to continue full-time telework in a post-COVID world."

[2] From the script: "…these staff on the left side of the screen. Collectively, they are FDA's official HR organization, and they are the only employees in FDA formally recognized as "HR staff". Center-based staff also provide HR support, including Human Capital Liaisons performing HR functions who are aligned within each Center's Office of Management."

HR support. Their customer service experience is impacted by the complexity of working with multiple HR points of contact, who often have different perspectives on processes, service delivery, and use of resources.

So, our Booz Allen assessment team brings extensive experience in human capital, organizational transformation, federal HR processes, and program evaluation. The team developed a comprehensive assessment framework and applied a standard four-step methodology to guide this Assessment, and you can see that here on the screen. The five assessment categories mirror those of the Interim Assessment, and our multi-method approach to data collection really enabled the team to gather both quantitative and qualitative data through objective and subjective methods. So, this included surveys, leadership interviews, focus groups with the Center and HR Workforces, HR data calls, and the review of data files and organizational documents. The team generated data-driven findings, synthesized the information to draw inferences across those findings, and then encapsulated these points as conclusions. And finally, the team developed 10 actionable recommendations to address gaps identified in the assessment. Now as expected with any organizational research, we did encounter some limitations, mainly related to the availability and reliability of data, although we will note that this has improved since the Interim Assessment. Limitations also included inherent potential for bias in qualitative, perceptual data, as well as limited data from the Initial Assessment to make comparisons over time. So we mitigated these limitations by instituting a multi-method approach, applying data quality checks and data cleaning procedures, and then corroborating findings. We also took these limitations into account when analyzing and interpreting the results.

So, now we will take a look at some of the key takeaways from the Final Assessment.

To start us off, we'd like to recognize that FDA has genuinely committed to the PDUFA VI and BsUFA II directive to improve its hiring and retention functions. Between the Initial and Interim assessments, FDA launched numerous initiatives to reimagine hiring solutions and lay the groundwork to address baseline HR challenges. In the limited time (essentially 10 months) between the Interim and Final assessments, FDA has made notable progress, with data reflecting more strategic thinking, collaborative activities, tangible outputs, and—in some cases—measurable impact. FDA also developed a roadmap for a common HRIT platform and invested in some enterprise-level data integrations and employee eSolutions. However, up until now each organization has mainly progressed to the extent that they can within their own operating unit and spheres of influence, which cannot fully address the fundamental challenges facing FDA. So in looking to the future, greater enterprise, FDA-wide coordination, influence, and investment is needed to achieve true HR transformation.

This slide here provides some more detail around FDA's progress made since the Initial Assessment.

To highlight just a few, in the 20 months following the Initial Assessment, FDA reorganized its official HR organization into two Offices to provide operational discipline and expertise in core HR areas and provide dedicated leadership focus. They reimagined the hiring workflow through a new Hiring Pilot, which ultimately did reduce the time-to-hire. They developed a new Applicant Tracking Solution,[3] (it's known as ATLAS) to support the hiring pilot and established critical governance and an alternate pay structure for the initial use of the 21st Century Cures Act Hire Authority, which is also known as Title 21. More recently, in the 10 months since the Interim Assessment, FDA further developed ATLAS to support more hiring processes, built a roadmap for future HRIT integration, and developed more detailed strategic

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[3] Full title: Applicant Tracking and Lifecycle Analysis Solution

documentation, including Service Level Agreements and Key Performance Indicators. They cleared the classification backlog and increased customer service and collaboration among staff performing HR work across different organizations. One important thing to call attention to is the relatively short 10-month timeframe to implement improvements since the Interim Assessment, as compared to the 20 months to implement from Initial to Interim. So going forward, FDA is going to need to tackle some of its most difficult issues at an enterprise level to make transformational improvements throughout its HR services. We will expound on this in detail through the rest of our presentation.

Dena Papazoglou:

Thanks Kristen, Now we're moving on to the results and recommendations section of our presentation.

I first want to take a moment and go over how the slides in this section are organized. First, we will speak to three cross-cutting themes that emerged from the assessment overall, followed by two cross-cutting recommendations that address those themes. Next, we will share specific information broken down by the five major categories of our assessment, as you see in the rows on the screen. Also, to help you follow along, we added these handy "breadcrumbs" at the top of each slide, and the category we are talking about will be highlighted as we go. For each category, we will present an overview of the results and recommendations, and we will note how the cross-cutting recommendations apply to the category.

So, as I just mentioned, three cross-cutting themes emerged from the assessment overall. Each of these themes relates to long-standing enterprise-level challenges that impact many aspects of FDA's HR functions, including recruiting, hiring, and retention. Over time, FDA has made strides in each of these areas, and the themes articulate the next-level ambitions for fully addressing these issues so they become enablers of transformational change. First, FDA needs a comprehensive HR Service Model that is led by OTS and OHCM but is jointly designed and committed to by all HR stakeholders with the services centered around the customer experience. The teal markers on the slide show this end-to-end integrated planning. In a similar vein, FDA would benefit from designing HR services as part an end-to-end Talent Experience Lifecycle, considering the employee perspectives from pre-application through separation, as shown in the dark blue circles. A very important detail here is to account for HR functions and Center-based management activities because they both have a major impact on the employee experience. And finally, it is essential to have an Enterprise HR Information Technology or HRIT system that can integrate data from across the different stages of the talent experience lifecycle. That integration is signified by the green chain links that run across the bottom.

These two cross-cutting recommendations reflect all three of the themes that we just discussed. What makes these transformational in nature is that they are enterprise-level solutions, which is necessary to fully address FDA's more fundamental challenges. The first recommendation (on the left) is to design an integrated HR service delivery model that focuses on customers and unifies the HR workforce. That would include coordinating end-to-end HR services (from recruiting and hiring through employee separation) and defining and deconflicting HR roles and responsibilities across all groups.

The second recommendation (on the right side) is to establish an enterprise-level HRIT system. That would include integrating data across recruiting, hiring, retention, and other HR functions, and using that data to inform HR strategies, support process automation, and enable sophisticated capabilities like dynamic workflow management and advanced analytics.

An important note is that while the focus of this study is CDER and CBER, many of these HR complexities and challenges are not necessarily unique to those Centers. Therefore, these cross-cutting recommendations could benefit all the Centers if they were executed enterprise-wide.

Now we will look to the specific results around our first category of Strategy. You can see how the breadcrumb at the top of the screen is green now. Results show that FDA has developed several noteworthy strategic planning documents. In particular, the Service Level Agreements and Talent Acquisition Plans established measurable goals for OTS and OHCM support for CDER and CBER.

These performance goals allow for objective progress monitoring, accountability for results, and HR performance data to support decision-making. A couple of other things to note: several of these strategic documents are specific to individual organizations, so they have limited power to effect broader change or strategic coordination across other organizations. Similarly, the strategic plans establish talent and hiring as a priority but need more specific guidance for how to implement that consistently, and they also lack an integrated view of how the recruiting, hiring, and retention functions are interrelated. And finally, although turnover in CDER and CBER has remained relatively low (at about 6-8%), consistent and targeted use of retention strategies and succession planning would help strategically retain the highest-priority, mission-critical skills in CDER and CBER.

Additional results for Strategy are related to COVID-19. The whole nation has some level of awareness about how much FDA was affected by the COVID-19 pandemic. While scientific, regulatory, and technical staff across Centers tackled mission-critical work, such as advancing the development of vaccines and treatments for the virus, the Agency's operational and administrative staff worked behind the scenes to quickly transform major aspects of HR service delivery. With that context in mind, it is not surprising that over half of all survey respondents reported that COVID-19 had a moderate to high impact on recruiting, hiring, and retention of CDER and CBER staff. As shown on the right, understanding the different types of impact can be useful to inform HR strategies in the future. On the positive side, both potential and current employees were inspired by FDA's public health mission and comforted by the stability of federal employment. And in the middle, the pivot to maximum telework and increased work flexibilities emerged as a mixed blessing. These flexibilities were very valuable to employees, to the extent that management worried about a surge in turnover if policies return to their pre-pandemic status. On the negative side, the pandemic brought a surge in workload and risk of burnout for CBER and CDBER staff and the HR workforce.

Our specific recommendation in this category is that FDA should refine its retention strategies. This refinement includes using data to establish which retention incentives are most effective for employees in different professions or life stages, and to help guide more consistent and targeted usage across the Agency. The retention strategies should also proactively incorporate succession planning, including the use of data to forecast upcoming needs and make plans to address them.

In addition, both cross-cutting recommendations will help FDA make broader strategic improvements beyond retention. First, the integrated HR Service Model would enable FDA to refine and tailor enterprise-level strategies for the end-to-end lifecycle and establish linkages between strategies and operational HR goals. Secondly, the Enterprise HRIT System would enable FDA to monitor progress towards strategic objectives and develop strategic initiatives with more precision, using integrated data in new ways such as process automation and predictive modeling.

Kristen Stanton:

Alright so, shifting over to our culture, collaboration, and communication category, results show measurable improvement since the Interim Assessment, but also clearly indicate that there is more work to do. Looking at the findings at the top left and right, OTS and OHCM have increased communication and collaboration with CDER and CBER, and their KPI tracking shows greater accountability for performance. But contrary to those results CDER and CBER staff also still say they need more engagement with OTS and OHCM and more documentation such as process guidance, checklists, and job aids. Now looking at the findings at the bottom left and right, there has been a substantial increase in both the percentages of Hiring Managers and the HR Workforce members who say that OTS and OHCM support has made them more satisfied with recruiting and hiring processes. So these results indicate that the changes that OTS and OHCM have made have had a positive impact on both receivers and providers of HR services. Despite this double-digit positive trend, the majority of CDER and CBER hiring managers indicated that OTS and OHCM support has not led to a substantial improvement in their satisfaction with recruiting and hiring.

So, continuing in looking at those results, as presented on the left, more stakeholders report that recruiting, hiring, and retention functions are meeting the needs of the Agency compared to Interim results. There was a modest increase for CDER and CBER Staff and a much larger increase for the HR Workforce. As shown on the right graph, survey results about the effectiveness of process handoffs is also a useful indicator of collaboration. Compared to Interim results, a higher percentage of HR Staff agree that the handoffs are effective for the process stages, but Managers of HR staff responses did not change that much, except for an increase in Interview and Selection, and a decrease in Recruiting.

As it pertains to Culture, Collaboration, and Communication, we recommend that OTS and OHCM engage their stakeholder engagement or—excuse me—enhance their Stakeholder Engagement Strategy to further increase collaboration with CDER and CBER. OTS and OHCM should use these interactions to recalibrate expectations that are held by all parties for HR service delivery and encourage two-way communication to increase transparency, build trust, and accelerate adoption of process improvement initiatives. Our cross-cutting recommendation regarding instituting an Integrated HR Service Model also applies in several ways here. It enables all staff performing HR work to adopt a unified, customer-focused mindset; it involves collaborating to further identify and document the ways the staff can gain HR efficiencies; and it builds shared commitment to the values and approaches that support different ways of thinking and interacting with customers.

Dena Papazoglou:

As a summary of the results in our next category, recruiting processes, FDA continued to attract qualified candidates and bolster its strategic outreach efforts. We will present some of the specific highlights here on the left side. OTS continued to build new external partnerships to increase and diversify its pipeline of scientific talent. FDA's website and social media presence continued to increase as well, and there was a commendable quick-pivot to virtual recruiting practices in 2020 as the pandemic shuttered in-person engagements. While the Centers still expressed an ongoing need for greater coordination and targeted outreach efforts, there is evidence that the Centers and OTS have come together to coordinate more on recruiting initiatives, such as FDA's presence at conferences. Centers have also worked hard on developing their own formal recruiting plans, trainings, and standardized practices, which again should be coordinated with guidance from OTS.

As shown on the right, results also indicate some opportunities to improve. In particular, recruiting and hiring data tend exist in separate, non-integrated sources, which hinders FDA's ability to measure and assess the effectiveness of recruiting activities. For example, if FDA could link new hires back to their recruiting source, it could determine which efforts yield the best outcomes and use that information to refine recruiting activities to meet targeted and diverse outreach needs.

Moving on now to specific results around hiring processes, there is no question that FDA faced an unprecedented hiring surge during the COVID-19 pandemic and responded with an "all hands-on deck" approach. As illustrated in the chart on the left, FDA was selective in using a variety of hiring authorities to fill over 1,300 CDER and CBER vacancies since the Interim Assessment. That's 16% more than those hired in Fiscal Years 18 and 19, and what's more, FDA has sustained this higher rate of hiring over the past two fiscal years; it wasn't just a temporary spike. The trend chart on the right-hand side shows that over the last three years CDER and CBER have begun using the Title 21 and Direct Hire Authority more actively, and it now makes up more than 50% of their overall hires. Stakeholders believe that Title 21 and Direct Hire are the most beneficial hiring authorities due to their efficiency and competitive salary options.

Now, continuing with our hiring process results, findings suggest that FDA's combined efforts, including various process improvements and targeted use of more efficient hiring options like Title 21 and Direct Hire, did reduce hiring process time. As shown in the light blue boxes on the right, our high-level conclusion is that FDA did complete hiring processes faster for both the Interim and Final timeframes. But there are a few things to note about this methodology, because this is not an apples-to-apples comparison. At the Initial Assessment, the time to hire was based only on interviews and focus groups about the process, rather than actual dates captured in a data system, and it covered only one hiring authority, Title 5. The Interim average time to hire reflects new procedures for one hiring authority, which is the Title 5 Hiring Pilot. These timeframes were derived from a data system, but the information on time to hire was not complete for all the hiring actions, and in the Final Assessment time to hire is an average of all the hiring authorities used since the Interim Assessment, not just the Title 5 process; and again, the information on time to hire was not complete for all the hiring actions. The checkmarks on the left highlight some of FDA's notable successes that helped bring about these process efficiencies, including OTS cleared the classification backlog and reduced classification processing time to an average of 37 days. OTS also improved workflow tracking and adopted KPIs to serve as accountability measures. And using shared certificates also reduced hiring process times in both the Interim and Final timeframes, saving an average of about 15 business days per hire. One other finding to call out is presented in the green circles on the top left. This shows that CDER and CBER selected only a small fraction of the candidates that OTS referred as being qualified for the position. At a minimum, these results show a great deal of fruitless effort by OTS to prepare those candidate referrals, and this pattern might contribute to overall inefficiencies in the hiring process. There are certainly reasonable explanations for a low number of selections; for example, there are only a certain number of vacancies to fill in the first place. But still, this finding suggests that there might be a difference in understanding and expectations of the candidate qualification procedures used by OTS staff and the quality of hire sought by CDER and CBER hiring managers.

This slide shows our two specific recommendations for recruiting and hiring processes. As FDA gains process efficiencies, it should continuously review and refine service delivery targets to maintain more efficient, yet sustainable, performance levels. And FDA should also examine the disconnect between OTS and Centers regarding their expectations of candidate

quality. In addition, both the cross-cutting recommendations will help improve recruiting and hiring processes as they become part of a seamless end-to-end customer experience. That includes investing in an enterprise HRIT system and an HR service model that bring together all of the HR process touchpoints. These enhancements would support data integrity and reporting, including insights on workflow metrics and workforce handoffs, to better understand the root cause of specific HR disconnects and better informed decision making and strategic planning.

Kristen Stanton:

Okay. We would now like to share the results around Data Management and Systems. The information on this page gives a simplified view of the data sources that are used in FDA's recruiting, hiring, and retention functions. OHCM has developed a well-thought-out roadmap for integrating these various data sources over time and making other ongoing HRIT system development improvements to help address data tracking and reporting challenges that were raised by the Initial and Interim Assessments.

Significant investment has been placed in the applicant tracking system, ATLAS, to specifically support the hiring function for the Agency. As a quick breakdown of the 11 systems that we consider "integrated" in this overview (and those are marked by the teal circle there), at the time of our data collection, three HR systems were fully integrated with ATLAS; although we will say that its data reporting capability was not yet functional so FDA was still relying on manual, stand-alone methods for tracking their data. Data from eight additional systems are scheduled to integrate with ATLAS in the coming month, which if deployed as planned will significantly improve data reporting for the hiring process and we will see data from several enterprise-wide employee applications. As for the four sources that are "intended for integration" initial planning is underway to incorporate data from these four supplementary Center-specific administrative management systems that were developed by CDER and CBER. However, these integration plans are still pending approval and funding. Lastly, there are at least 10 additional data sources that are manually maintained by individual organizations. And as the ATLAS system has been purposefully designed and developed for the hiring function, even after upcoming planned deployments there will still continue to be gaps in linking hiring data with recruiting and retention data, especially around talent sourcing and offboarding. The larger service platform upon which ATLAS is built does have the capabilities to support such end-to-end data integration, but there are no active plans underway to do so at this time.

So, qualitative data also underscored the point that stakeholders want to see an investment in the integrated Agency-wide HRIT platform. About half of the HR workforce and two-thirds of CDER and CBER staff indicated that a reliable, transparent HRIT system would make HR processes more successful, and interview and focus group participants further noted that the non-integrated systems lead to more errors, inefficiencies, and lack of transparency.

So, we have several recommendations for FDA; ways that FDA can address the broader systemic integration and data management issues that continue to challenge their service delivery. As shown in the lime green pyramid on the slide, FDA should continue to infuse more uniformity and structure into data management and reporting practices and that will improve HR data integrity, access to data, and the confidence others have in data to drive business decisions at FDA. In addition, FDA should encourage two-way communication between OTS/OHCM and Center HR stakeholders to increase awareness and efficient adoption of improvements to data management systems. And of course the cross-cutting recommendation of an Enterprise HRIT System is vitally important for FDA to make lasting

improvements in this area. Specifically, Centers and OTS/OHCM should work together to unify data practices and develop a single enterprise HRIT infrastructure solution that integrates end-to-end data and HR processes. This solution should include advanced system capabilities such as seamless workflows, tracking, and reporting for all the HR functions, from anticipated vacancy through separation. Investing in an enterprise-level solution brings major advantages, including greater vested interest, pooled resources, commitment, and accountability for delivering an optimized talent experience.

Dena Papazoglou:

[inaudible]

Kristen Stanton:

Dena, you are on mute.

Dena Papazoglou:

Thank you, sorry about that. Moving on to the results for our last assessment category, this slide focuses on HR Staff Capability, which has to do with the skills and abilities of the HR staff. As shown in the checkmarks on the left, FDA has implemented various capability-building initiatives to establish performance expectations and development of HR staff or staff performing HR work across the agency. Specifically, OTS's assessments, leadership coaching, and competency framework and CBERs new SharePoint HR resource hub are excellent examples of advancing staff HR capabilities and performance. However, it is important to note that these initiatives are currently operating independently within individual organizations and not across the entire HR workforce. To build a cohesive workforce, these kinds of development opportunities would ideally be applied to staff performing HR work in Centers and Offices across FDA to help improve the quality and consistency of HR staff capability overall. Results on the right show measurable improvements that are consistent with these efforts to enhance HR staff capability. This chart shows that more respondents have positive views of HR staff capability compared to the Interim Assessment. Specifically, more managers rated their HR staff as proficient, with an increase of at least 13 percentage points for all the technical HR competencies, the biggest increases being in Recruitment and Federal HR Technical Knowledge, which are presented in the top two bars. Also, more CDER and CBER Hiring Managers reported being satisfied with the abilities of OTS HR Specialists, with an increase of at least nine percentage points across the board. As shown in the bottom two bars, the biggest increases were for Applying Knowledge of HR Policies and Procedures and Meeting Timelines and Commitments. Despite these positive trends, it is also important to note that less than a quarter of hiring managers currently report being satisfied with the abilities of OTS HR Specialists, as reported on the Final Assessment Survey. So although measurable progress is happening, there is still a lot of room for improvement.

Now we will look at results around HR Staff Capacity, which has to do with the availability of knowledgeable HR staff to manage the HR workload, which includes providing services to its customers. FDA's official HR servicing ratio is currently 1:59, as shown on the left. The ratio means there is one HR Specialist in OTS and OHCM for every 59 FDA employees. A technical detail to note here is that the role of HR Specialist is the only one officially recognized as "HR Staff" by the Office of Personnel Management, so they are used for this equation even though there are other FDA staff who perform HR work. So even though this is not perfect, this standard way of calculating the ratio is helpful because it can be compared with other agencies and tracked as a trend over time.

On that note, FDA's HR servicing ratio has remained stable since the Interim Assessment, when it was 1:60. Another way to look at HR Staff Capacity is to account for all the staff who are performing HR work for CDER and CBER, which, as you can see on the right-hand side, includes an estimated 186 "Full Time Equivalents (FTE)" from OTS, OHCM, CDER, and CBER. OTS and OHCM provide services to the whole FDA workforce, so these numbers show the estimated proportion of their support that is devoted to CDER and CBER. This total also reflects the proportion of CDER and CBER staff support that is dedicated to HR work for their respective Center. These results highlight how the Centers continue to invest heavily in their own dedicated staff to supplement the HR support provided by OTS and OHCM. It is also important to consider that these separate groups are providing HR support to the same "customers"—CDER and CBER. Without close coordination and careful management between all these different organizations, there is a high risk of process inefficiencies and duplication of effort in this situation.

[INAUDIBLE]

Our assessment generated several recommendations for FDA to continue improving HR Staff Capability and Capacity. The cross-cutting Integrated HR Service Model recommendation applies here, especially as it relates to defining and de-conflicting the formal roles and responsibilities of the six distinct groups of staff who provide varying types of HR support. Doing so sets the foundation for the additional recommendations shown on the slide that apply to all staff performing HR work across organizations. These recommendations include refining processes for measuring, assessing, and distributing work; developing and implementing a unified competency model that supports customer-focused performance expectations, workforce planning, and succession planning; and finally, standardizing HR performance goals and holding managers accountable for actively managing HR workforce performance.

Kristen Stanton:

Thank you, Dena. So that concludes our assessment results and recommendations. Regarding next steps: now that the Final Assessment is complete and the public report is published, the public has through May 15th to provide comments. Booz Allen will then work with FDA to develop its implementation plan with regards to addressing the Final Report recommendations. Also, FDA has committed to another evaluation of its progress in 2024/2025 to meet new PDUFA VII and BsUFA III commitments.

So, simply for reference, we have also included a high-level summary slide of our conclusions and recommendations for each of the categories, and that can be seen here.

We really appreciate the confidence in FDA that they have placed in Booz Allen to conduct these past two assessments. I'm now going to turn it over to Melanie Keller, Director of the Office of Talent Solutions, to deliver an update on FDA's Response to this Final Assessment. Melanie?

Melanie Keller:

Thank you, Kristen and Dena. Our colleagues at Booz Allen Hamilton did an exceptional job outlining both our substantive progress and we recognize that there is more work to do.

[Inaudible] FDA appreciates the results and recommendations found in this Final Report and we have made tremendous progress since the first assessment back in 2017; and although we are a very different organization since 2017, we are happy to have our familiar face in Dr. Califf, back as our Commissioner. We are really proud particularly of the fact that we have

partnered with our Centers and offices to establish hiring goals, and we have met or exceeded them in FY20 and FY21. Specifically, FDA hired 2,789 staff from the start of the pandemic through January 2022, and 41% of those hires were in CBER and CDER. We have also maintained a relatively low attrition rate, and we are also very proud that we have deployed the Applicant Tracking Lifecyle and Analysis System (ATLAS) to CBER and CDER for real time tracking and accountability. This is the tool that we had vision that tracking hiring should be as easy as when you order a pizza in the way you can tell when it is in the oven and when it is being delivered. With ATLAS, we have the capability to track every step in the hiring process, and there is very clear accountability for who owned that step, how long it took, and where things are. So, we really have come a long way with this. We have also continued to enhance our focus on Diversity, Equity, Inclusion, and Accessibility (DEIA). This is a major initiative for FDA, and it will help expand our candidate pool and bring in new and exciting talent. We have also accomplished everything that Booz Allen Hamilton mentioned during the unprecedented pandemic that has really radically transformed our workforce, and the impact of that is still being felt. We have had to pivot to be completely remote and online, our outreach and recruitment efforts did also have to pivot, and despite all of that, we were still able to achieve incredible hiring and retention results.

So, since the first and interim assessment we have made a lot of progress. Many of the recommendations that our colleagues from Booz Allen Hamilton mentioned were already underway, and now we are expanding our focus. I do want to mention that we have been trying really hard as an agency to keep the hiring and retention engine running to meet the ever-expanding needs of our hiring managers and our workforce, as well as working on recommendations to optimize our strategies and processes and systems. So, we have been trying to balance it all. One of our major initiatives that has been a major finding and recommendation is being led by my colleague, Tania Tse, the Director of Office of Human Capital Management, and she is leading and we are developing a unified agency-wide strategic human capital plan. As Kristen and Dena mentioned, we have many strategic planning documents – the centers have them, we have them – and they are for different parts of the talent lifecycle, but this overarching plan will cover the entire process for the entire agency. So, we are excited about that. And as you have learned and as our chart shows here, there are lots of staff involved in the hiring process, and we have improved our ability to work together to achieve incredible hiring results for the agency. And we are launching an initiative where we will identify and be clear about roles and responsibilities for our workforce that support hiring and retention to have a customer-focused delivery model so that we are as lean and agile as possible with a focus on speed-to-hire, quality, customer satisfaction, and of course legal compliance. Finally, we are partnering with the FDA Chief Information Officer, Vid Desai, and his team to analyze digital solutions that integrate the entire FDA talent lifecycle, which has also been an important and recurring recommendation. Again, we are grateful for the recognition of progress, particularly during an unprecedented global pandemic, and we appreciate the invaluable feedback and recommendations. We look forward to making even more progress within the FDA so that we can continue to recruit and retain the world-class workforce that is so necessary to deliver on our mission for the American people. I will now turn it back over to Yashika Rahaman.

Yashika Rahaman:

Thank you, Melanie, for providing FDA's response, and also thank you Booz Allen for presenting your assessment results and recommendations. I know that this continues to be a high-priority focus area for FDA with commitment for the continual advancement of the Agency's HR functions. And so, at this time, we will open the floor for questions from the audience.

Okay, we have now opened, hopefully you see it, the participation chat feature at the bottom of your screen, where you can submit your questions and comments. You can also submit questions and comments outside of this meeting online at regulations.gov through May 15th. Please note that your questions and comments will be recorded as a part of the meeting transcript for public record. Okay. So, I am looking in the chat now and we are awaiting any questions or comments that you may have. Hopefully everyone is able to find the chat box; on mine it is in the bottom left-hand corner, hopefully you can see it there. We will give it another minute or so to see if anyone is still thinking through their questions and comments.

Alright, seeing no questions in the chatbot or comments, that will conclude our session for today. A transcript of this meeting and a copy of this presentation will be published in the coming week. Thank you all for joining. Have a wonderful rest of your day, and if you think of any questions or comments again after this meeting, you can submit them through regulations.gov through May 15. Thank you once again for your time.