



Public Meeting on the FDA Interim Hiring and Retention Assessment

Public Meeting
July 30, 2020
9:00 AM – 11:00 AM



9:00 – 9:05 AM

WELCOME AND INTRODUCTION

Ema Kamara

Director [Acting]

Office of Planning and Evaluation | Office of Operations

Agenda



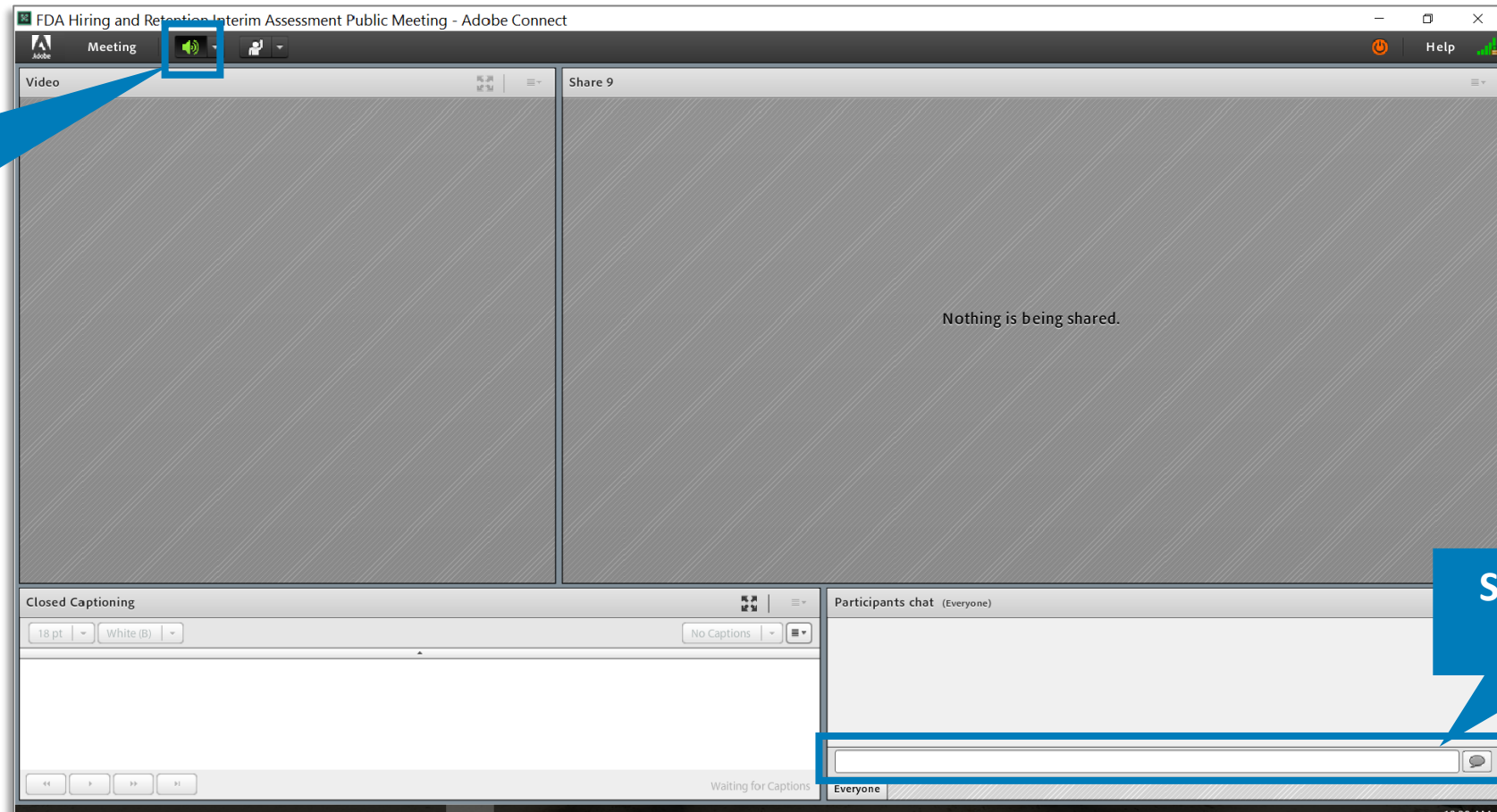
Topic	Presenter	Time
Welcome and Introduction	Ema Kamara Director [Acting] Office of Planning and Evaluation Office of Operations	9:00 AM – 9:05 AM
Background of PDUFA/BsUFA Hiring and Retention Commitments	Andrew Kish Director Office of Program and Strategic Analysis CDER	9:05AM – 9:10 AM
Interim Assessment Overview	Elaine Brenner, Ph.D. and Kristen Stanton Booz Allen Hamilton	9:10 AM – 9:40 AM
FDA Update on Response to Interim Assessment	Melanie Keller Director Office of Talent Solutions Office of Operations	9:40 AM – 10:00 AM
Open Public Comment	Ema Kamara Director [Acting] Office of Planning and Evaluation Office of Operations	10:00 AM – 11:00 AM

How to Submit Questions at the End of the Meeting



- Submit your questions at the end of the presentation via the Adobe chat box
Please use the following format: *Name, Organization: Comment*
- Questions/comments will be recorded as part of the meeting transcript for public record

To hear audio,
make sure your
audio icon is
green 



Submit your
questions

How to Submit Comments on the Public Docket



Comments can also be submitted through September 30, 2020 via the public docket at <https://www.regulations.gov/document?D=FDA-2020-N-1500-0001> or by searching “Hiring and Retention Interim Assessment” at www.regulations.gov

The screenshot shows the regulations.gov website interface. At the top, there is a navigation bar with links for Home, Help, Resources, and Contact Us. A search bar is located in the top right, containing the text "Hiring and Retention Interim Assessment". Below the search bar, the main content area displays a notice titled "Food and Drug Administration Hiring and Retention Interim Assessment; Public Meeting; Request for Comments". A prominent "Comment Now!" button is highlighted with a blue box. The page is divided into sections: "Action" (Notice of public meeting; request for comments.), "Summary" (The Food and Drug Administration (FDA, the Agency, or we) is holding a virtual meeting entitled "FDA Hiring and Retention Interim Assessment" and an opportunity for public comment...), and "Dates" (The public meeting will be held on July 30, 2020, from 9 a.m. to noon...). On the right side, a "Document Information" sidebar provides details: ID: FDA-2020-N-1500-0001, Date Posted: Jul 13, 2020, Federal Register Number: 2020-14980, and a "Show More Details" link. Social media sharing options for Tweet, Share, and Email are also visible.

Search

Select
"Comment Now"

9:05 – 9:10 AM

BACKGROUND OF PDUFA/BSUFA HIRING AND RETENTION COMMITMENTS

Andrew Kish

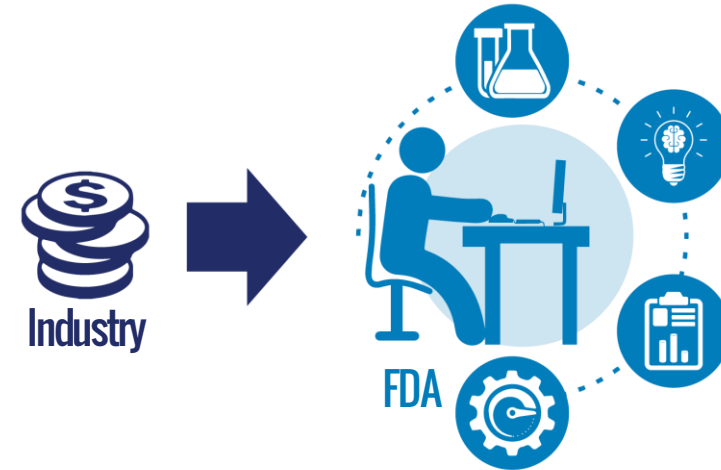
Director

Office of Program and Strategic Analysis | CDER

Background of PDUFA and BsUFA Hiring and Retention Commitments



- FDA is authorized to collect user fees from sponsors and applicants to help expedite the development, review, and approval processes of human drug and biologics.
- As part of PDUFA VI and BsUFA II commitments, FDA is conducting a series of three assessments of its hiring processes as well as its hiring staff capacity and capabilities that contribute to achievement of successes, potential problems, or delays in hiring human drug and biologics review program staff.



FDA contracted with Booz Allen—as a third-party evaluator—to conduct this Interim Assessment



9:10 – 9:40 AM

INTERIM ASSESSMENT OVERVIEW

Elaine Brenner, Ph.D.
Booz Allen Hamilton

Kristen Stanton
Booz Allen Hamilton

Interim Assessment Background

FDA HIRING CHALLENGES

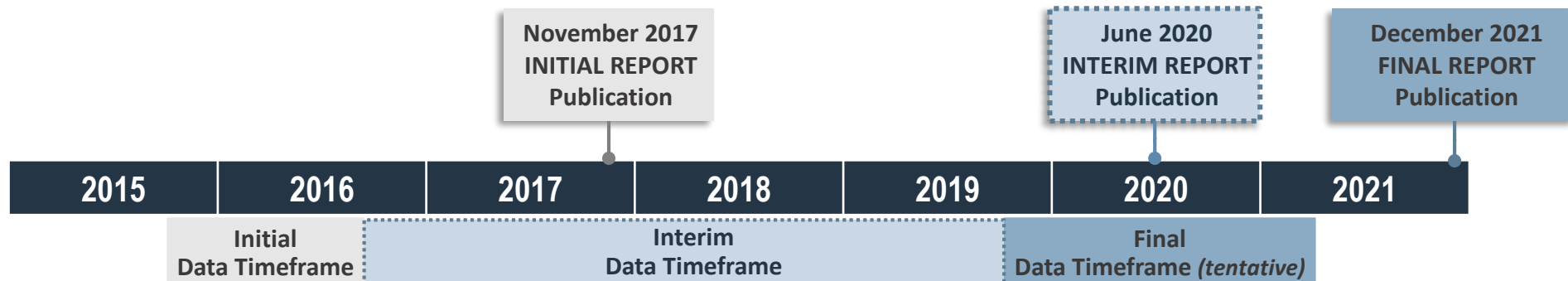
FDA continues to face the ongoing hiring challenges identified in the Initial Assessment in November of 2017 as well as FDA's Cures Workforce Planning Report to Congress in May of 2018.

- **“War for Talent”** – the rapid speed of medical and scientific advancements has increased competition with the private sector and academia for talent with unique and specialized skills
- FDA's long history of internal HR complexities are compounded by **varying degrees of collaboration** among interdependent HR stakeholders
- An Office of Personnel Management (OPM) Audit in 2018 uncovered **significant issues with FDA's delegated examining (DE) activities**
- Almost **half of FDA's senior leaders are retirement-eligible** in FY20

INTERIM ASSESSMENT PURPOSE & TIMELINE

Purpose

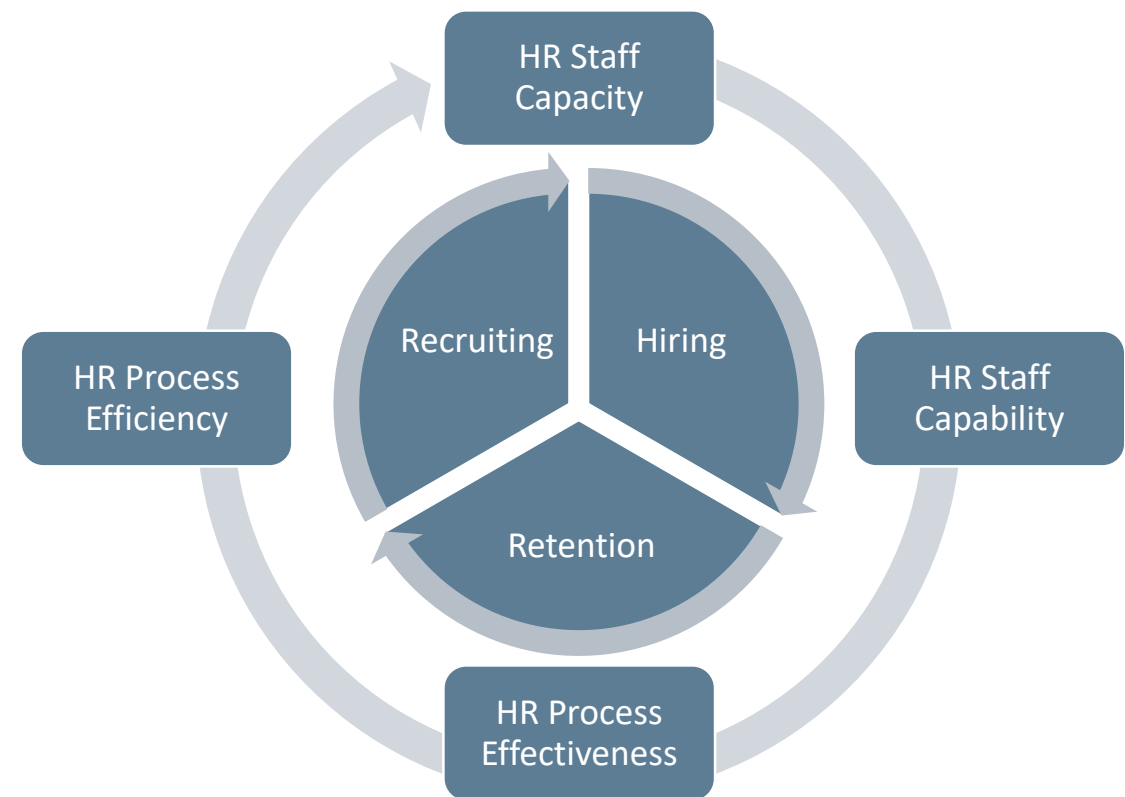
- Assess FDA's ability to recruit, hire, and retain human drug and biologics review program staff (i.e., CDER and CBER staff)
- Provide recommendations based on identified gaps or areas for improvement



SCOPE OF INTERIM ASSESSMENT

- Progress since the Initial Assessment
 - Initial recommendations
 - Data comparison
 - Effectiveness of five identified improvement activities
- Current state of recruiting, hiring, and retention
- Recommended improvements

Our assessment looked at **4 key focus areas**
across **3 HR functions**

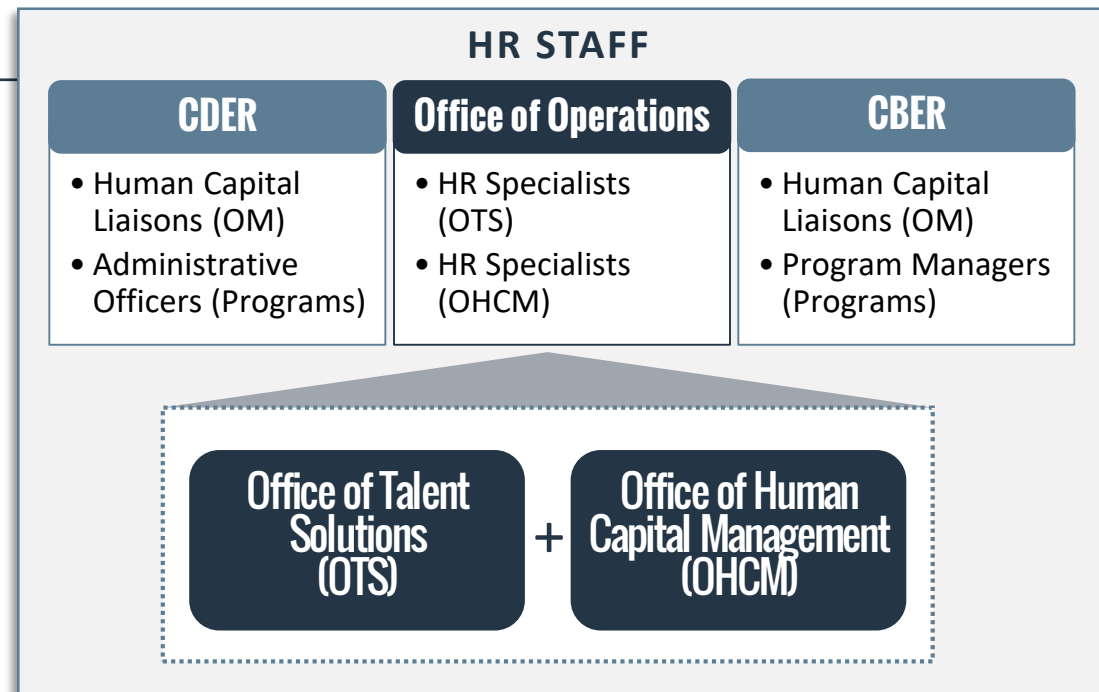


FDA HR STAKEHOLDERS

There are a large number of FDA stakeholders impacted by recruiting, hiring, and retention activities. Staff performing work related to HR functions are aligned not only within the Agency's HR Organization (i.e., OTS and OHCM) but also within each Center's Office of Management and program offices.

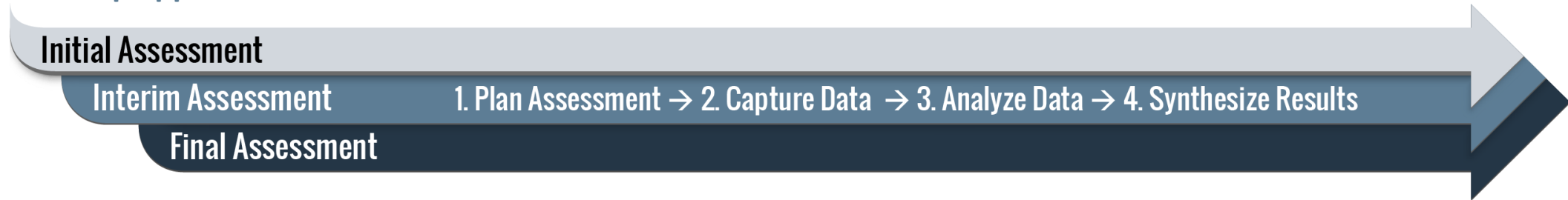
FDA HR STAKEHOLDERS

- HR Staff
- Human Drug and Biologics Review Program Staff in CDER and CBER
- Hiring Managers
- Managers of HR Staff
- HR Senior Leadership
- FDA and Center/ Office Leadership



ASSESSMENT DESIGN AND METHODOLOGY

Four-step approach to conduct the second of three assessments



Multi-method data collection



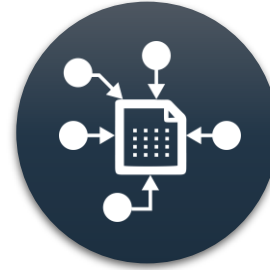
Integrated, data driven results



ASSESSMENT LIMITATIONS



Limited availability of reliable data



Some FDA data captured, tracked, and maintained inconsistently and in multiple places



Inherent potential for bias in qualitative, perceptual data

Potential for different interpretation of key terms by study participants



Limited data and procedural documentation from the Initial Assessment to make comparisons over time

Progress Since Initial Assessment

PROGRESS AGAINST IMPROVEMENT ACTIVITIES THAT FOLLOWED THE INITIAL ASSESSMENT

A key component to the Interim Assessment included looking at the progress against five improvement activities identified by the FDA since the Initial Assessment.

Levels of Implementation Progress

Optimized: Activity is fully implemented, widely known and embraced within CDER and CBER, and measurably transforming recruitment, hiring, and/or retention.

Integrated: Activity is partially implemented, gaining awareness within CDER and CBER, and has made some incremental improvements to recruiting, hiring, and/or retention.

Foundational: Activity is designed but not yet implemented, is not yet well known among CDER and CBER, and has not yet demonstrated impact to recruiting, hiring, and/or retention.



- The **Initial Assessment** identified **3 key recommendations** focused piloting a redesigned hiring process
- This led FDA to implement the **Scientific Talent Recruiting Staff (STRS) Hiring Pilot** and **4 other improvement activities**
- Booz Allen developed a simple maturity model with three levels of implementation—**Foundational, Integrated, and Optimized**—from which to assess progress

FIVE IMPROVEMENT ACTIVITIES

All five improvement activities fell in the **Integrated** level of progress, given their partial implementation, basic awareness by CDER and CBER, and incremental impacts to HR functions. To reach the **Optimized** level of progress, the activities will need to be fully implemented, widely embraced, and measurably transform HR functions at FDA.



PROGRESS: SCIENTIFIC TALENT RECRUITING STAFF (STRS) HIRING PILOT

The STRS Hiring Pilot has demonstrated some incremental improvements to hiring; however, because of data limitations, it is not yet possible to determine if the improvements are repeatable for groups outside the Pilot.

Representative Accomplishments To Date:

- ✓ Demonstrated reduced time-to-hire through its streamlined process
- ✓ Demonstrated time-savings through the use of shared certificates
- ✓ Introduced applicant tracking with the ATLAS system
- ✓ Created a new Talent Strategy Officer role to improve communications with Hiring Managers

Success Story

Tracked Hiring Pilot data indicate time savings are achievable through the use of shared certificates:

- **Saved between 15 and 53 days** in end-to-end time-to-hire
- Over **60% faster** than stand-alone certificates

Recommended Next Steps:

- ❑ Improve data management and reporting capabilities (R-4, R-6) tied to outcome/success measures (R-17)
- ❑ Expand system integrations (R-12)
- ❑ Increase pilot communication products (R-12)
- ❑ Create a centralized knowledge management repository for pilot documentation and communications (R-15)

PROGRESS: OFFICE OF HUMAN RESOURCES (OHR) REORGANIZATION

The OHR reorganization established a foundation for a strategic, systematic approach to recruiting, hiring, and retention, with incremental progress in establishing internal governance and operations. However, Centers are unclear about the reorganization's purpose and intended benefits and have not yet observed meaningful improvements.

Representative Accomplishments To Date:

- ✓ Instituted new levels of management focused on the Centers
- ✓ Separated pre-employment activities from employee experience services
- ✓ Centralized dedicated teams with functional expertise to enhance quality control and scalability for critical or specialized hiring components
- ✓ Enhanced HR employee accountability with new HR performance management action plans

Success Story

Launch of *Talent Academy* for mandatory OTS-wide training

Success Story

100% of HR staff in OTS now have consistent performance standards in their PMAPs

Recommended Next Steps:

- ❑ Design a well-coordinated organizational strategic plan (R-2)
- ❑ Create a stakeholder engagement strategy (R-11) and tactical communication products (R-12)
- ❑ Foster a collaborative, customer-centric culture (R-10) and reframe roles (R-7)
- ❑ Develop workload management processes and tools (R-8)



*Note: While OHCM manages work-life retention programs, OTS manages monetary retention programs and incentives.

PROGRESS: 21ST CENTURY CURES ACT

FDA has taken the time to establish critical foundational planning and governance for use of the 21st Century Cures Act hiring authority but hiring is still relatively low and mainly internal. The focus now needs to extend to Cures' hiring goals and outcome measures to evaluate effectiveness.

Representative Accomplishments To Date:

- ✓ Made 47 appointments across CDER and CBER (data through Sept 30, 2019)
- ✓ Implemented governance structure, including a HR Cures Working Group and Steering Committee
- ✓ Designed and implemented a new Alternative Pay Structure (APS)

Success Story

Delivered a mandated FDA Workforce Planning Report, Recruiting and Retention Plan, and Recommendations to Congress

Recommended Next Steps:

- ❑ Create a strategic stakeholder engagement strategy (R-11) along with a detailed communication plan (R-13) and tactical communication products (R-12) regarding FDA's procedures and use of Cures
- ❑ Define outcome/success measures (R-17) tied to specific hiring goals and targets (R-3)

Current Cures data (below) are not tied to specific hiring targets:

- **Only 9%** of all **CDER** hires in FY19 were Cures hires
- **Only 2%** of all **CBER** hires in FY19 were Cures hires

PROGRESS: SCIENTIFIC STAFFING TEAM (SST)

The new Scientific Staffing Team has made great strides in increasing external strategic partnerships and building a unified FDA online presence. However, based on interviews and focus groups, Center staff expressed limited awareness of the SST's scope and impact as well as concerns of limited coordination with the Centers.

Representative Accomplishments To Date:

- ✓ Generated a unified FDA recruitment brand and presence at external events
- ✓ Created 100+ external partnerships to develop a pipeline of highly qualified candidates with a focus on STEM talent
- ✓ Launched new FDA social media presence; increased online traffic
- ✓ Hosted 12+ academic visits in 2018 and 2019
- ✓ Introduced a recruiting effort for Veterans and persons with disabilities

Recommended Next Steps:

- ❑ Create a strategic stakeholder engagement strategy (R-11) and tactical communication products (R-12) with a collaborative, customer-centric culture (R-10)
- ❑ Identify outcome/success measures (R-17) tied to specific hiring goals/targets (R-3)

Success Story

New social media presence resulted in a substantial increase of online traffic from September 2018 to September 2019

FDA Jobs
Page Views
Per Month  **>1000%**

Twitter
Total Followers  **>123%**

LinkedIn
Total Followers  **37%**

PROGRESS: EXPANSION OF DIRECT HIRE AUTHORITY

Both CDER and CBER leveraged the DHA expansion to hire STEM and Cybersecurity staff in FY19. However, similar to Cures, DHA hires remain a small fraction of total human drug and biologics review program staff hires.

Representative Accomplishments To Date:

- ✓ 100% of CBER Direct Hires and 30% of CDER Direct Hires in FY19 were associated with the authority's expanded positions

Success Story






CDER's FY19 Personnel Action Plan prioritizes the use of DHA for hiring certain positions

Recommended Next Steps:

- ❑ Create a detailed communication plan (R-13) and tactical communication products (R-12) regarding OPM requirements for and FDA's procedures and use of DHA
- ❑ Define outcome/success measures (R-17) tied to specific hiring goals and targets (R-3)

Only 12% of total gains for both CDER and CBER in FY19 were associated with the expansion of DHA

COMPARISON WITH INITIAL ASSESSMENT'S FINDINGS

INITIAL ASSESSMENT*			INTERIM ASSESSMENT
Findings	Implications		Extent of Progress Made
Process documentation is incomplete	Substantial variation in execution	▶	 <p><i>Minimal progress</i> Some process documentation updated.</p>
Process suffers from substantial complexity	Poor timeliness and customer satisfaction	▶	 <p><i>Little to no progress</i> Stakeholders remain very dissatisfied with timeliness and process complexity.</p>
Unclear roles and responsibilities	Confusion and weak accountability	▶	 <p><i>Minimal progress</i> Some training and performance standards provided to HR staff.</p>
Poor user friendly technology and systems	Low efficiency and transparency	▶	 <p><i>Minimal progress</i> ATLAS designed to address some issues with efficiency and transparency.</p>
Lack of collaborative open dialogue	Poor communication	▶	 <p><i>Little to no progress</i> Stakeholders report ongoing lack of collaborative open dialogue.</p>

*verbatim from Initial Assessment public meeting presentation

Interim Assessment Results and Recommendations

INTERIM ASSESSMENT - KEY TAKEAWAYS

KEY CHALLENGE AREAS



Strategy



Data Management
and Systems



HR Staff Capability
and Capacity



Culture,
Collaboration, and
Communication



Recruiting and Hiring
Processes

SUMMARY OF RECOMMENDATIONS

Develop an enterprise human capital strategy that addresses the dynamic nature of recruiting, hiring, and retention and integrates Center-specific hiring plans

Enhance tools, procedures, and accountability for data curation, management, and reporting

Establish clear, standardized workload management processes, performance goals, and accountability for HR staff across FDA

Foster more collaborative, customer-centric engagement between the Centers and OTS/OHCM—focused on shared HR goals, knowledge sharing, and effective communications

Streamline and document recruiting and hiring processes and outcome measures, resolve the classification backlog, and build an official, centralized repository of process guidance



RESULTS: STRATEGY

CONCLUSIONS

Conclusion 1

- FDA lacks an enterprise-wide systems approach to integrate and optimize recruiting, hiring, and retention
- OTS/OHCM and the Centers have made some noteworthy strategic efforts

Conclusion 2

- Overall turnover at CDER and CBER is relatively low
- Staff are committed to working for the Agency
- FDA lacks a strategic approach to quickly recover when they lose specialized talent

RECOMMENDATIONS

- Assess the strategic alignments among recruiting, hiring, and retention to identify and leverage their linkages
- Develop and implement an integrated human capital strategic plan with enterprise-wide, time-bound goals and actionable steps
- Integrate Center hiring targets into a unified strategic hiring plan to prioritize recruiting efforts

Note: Conclusions and recommendations are abbreviated for presentation purposes. Full versions can be found in the Interim Hiring and Retention Assessment Report (see Conclusions C1-1 and C1-2 and Recommendations R-1, R-2, and R-3).



RESULTS: STRATEGY

Despite relatively low turnover, CDER and CBER net gains are limited and the Centers struggle to recover from losses of specialized talent because of a lack of an integrated strategy across HR functions

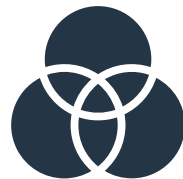
Attrition rates are low across CDER and CBER, except for a few occupations and offices

5% CDER Attrition vs. 16% attrition across Federal Government
6% CBER Attrition

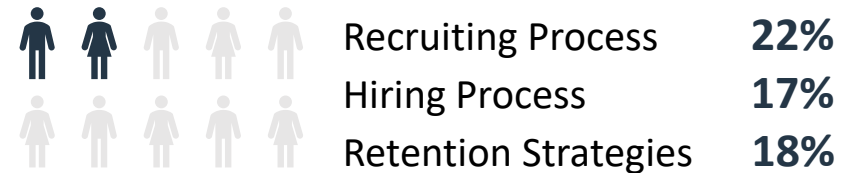
Hiring is exceeding losses, but with minimal net gains



Current FDA strategic plans do not address the interrelated cycle of recruiting, hiring, and retention



Few stakeholders agree HR processes meet FDA's needs





RESULTS: DATA MANAGEMENT AND SYSTEMS

CONCLUSIONS

Conclusion 1

- Deficiencies in HR data collection and management result in inefficiencies and inhibit measurement of HR efforts

Conclusion 2

- FDA's technology integration is not yet mature enough to sustain data integrity, data access, and reporting agility

RECOMMENDATIONS

- Put more uniformity and structure into data management and reporting practices
- Compile an inventory of major HRIS technologies used
- Develop a map showing the linkages across major HRIS technologies for CBER and CDER
- Employ additional technological solutions to enhance data management and reporting capabilities

Note: Conclusions and recommendations are abbreviated for presentation purposes. The full versions can be found in the Interim Hiring and Retention Assessment Report.



RESULTS: DATA MANAGEMENT AND SYSTEMS

Data Management and Systems issues documented in the Initial Assessment continue to challenge the effectiveness of recruiting, hiring, and retention. Systems are **not integrated, not automated and not efficient.**

Incomplete Data Capture

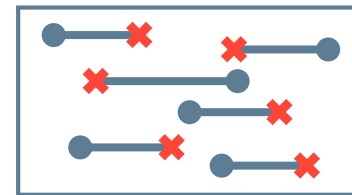
...Limits ability to address HR challenges and monitor progress



- ✗ HR Performance Indicators
- ✗ Hiring Process Times
- ✗ Recruitment Outcomes
- ✗ HR Staff Performance Management
- ✗ HR Staff Organization Alignment and Workload Distribution
- ✗ Vacancies by Center
- ✗ Position Management Details

Multiple Data Systems

...Perpetuate lack of automation, accuracy, and efficiency



6+ systems
used for the hiring process

When **ATLAS** is fully implemented, this technology has the potential to improve some hiring data challenges:

- **Transparency** among stakeholders
- **Time-to-fill tracking**
- Increased **accountability**
- **Quality control** for process-stage data



RESULTS: HR STAFF CAPABILITY AND CAPACITY

CONCLUSIONS

Conclusion 1

- The OHR reorganization established some important building blocks
- FDA lacks a comprehensive organizational infrastructure for HR to enable consistent, high-quality service delivery

Conclusion 2

- FDA faces issues with both HR staff capability and capacity
- FDA does not sufficiently track HR workload management, competencies, and performance to enable a complete understanding of the root causes of these issues

RECOMMENDATIONS

- Reframe the roles of OTS' HR staff aligned to CDER and CBER as "HR Business Partners."
- Establish a workload management process for assessing and distributing work across the HR workforce, leveraging reliable analytic tools
- Establish standardized PMAP goals to hold managers of HR staff accountable for actively managing staff performance agency-wide

Note: Conclusions and recommendations are abbreviated for presentation purposes. The full versions can be found in the Interim Hiring and Retention Assessment Report.



RESULTS: HR STAFF CAPABILITY AND CAPACITY

HR Staff Capability: The lack of a consistent set of competency requirements inhibits HR staff from building common behavioral expectations, training protocols, and standard proficiency requirements to do the work.

Managers of HR Staff are mainly confident with HR Staff capability, with the exception of Classification.

Managers of HR Staff surveyed reported that:

90% of HR staff are *proficient* in HR **Core Competencies**

42% of HR staff *do not meet* **Classification Technical Competency** requirements

Hiring Managers are mainly dissatisfied with HR Staff capability

5-8% of Hiring Managers are *Satisfied* or *Very Satisfied* with the HR Staff in **FDA's HR Organization (OTS and OHCM)**

12-19% of Hiring Managers are *Satisfied* or *Very Satisfied* with the HR Staff in **Centers' Office of Management**

39-46% of Hiring Managers are *Satisfied* or *Very Satisfied* with the HR Staff in **Center Program Offices**



RESULTS: HR STAFF CAPABILITY AND CAPACITY

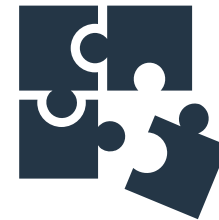
HR Staff Capacity: While FDA's HR Servicing Ratio appears to be consistent with benchmarks, it is difficult to determine with certainty if the ratio is effective due to vacancies and the distribution of HR staff across FDA.

FDA's HR Servicing Ratio is **1:60**, and is consistent with HR Servicing Ratio benchmarks



- 1:63** Established by OPM in FY12
- 1:49** GSA study in 2016 (for HHS HR)
- 1:53** GSA study in 2016 (for all Federal government agencies)

However, the HR function is understaffed due to persistent high vacancies



- 21% vacancies** of HR Staff in OTS supporting CDER and CBER
- 27% vacancies** of HR staff in CBER OM
- 15% vacancies** of HR Staff in CDER OM

In addition, HR Staff are decentralized across FDA OO, CDER, and CBER, which creates difficulties:

- ?** • Determining an accurate workforce count
- Assessing workload distribution



RESULTS: CULTURE, COLLABORATION, AND COMMUNICATION

CONCLUSIONS

Conclusion 1

- The hiring process is overwhelmingly considered to be inefficient and ineffective
- Better communication, collaboration, process documentation, and guidance are key for improvement

RECOMMENDATIONS

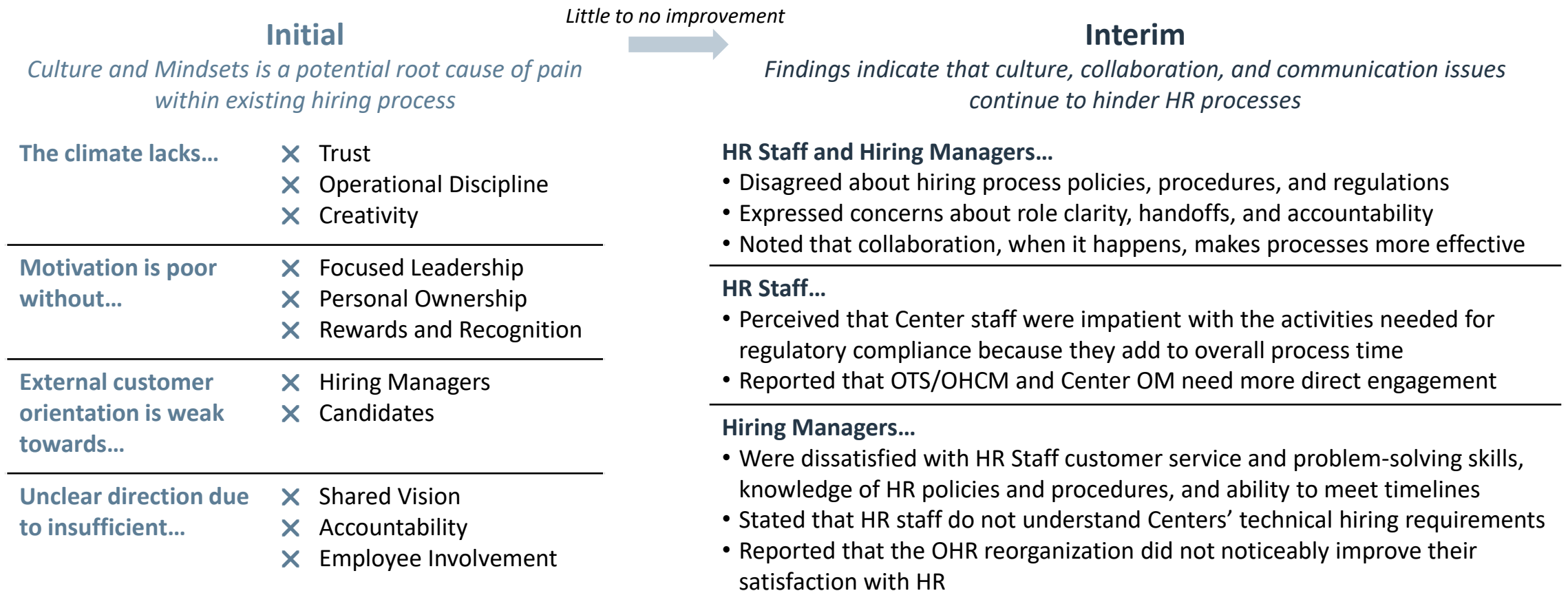
- Shift to a more collaborative, customer-centric culture
- Establish a stakeholder engagement strategy to encourage two-way communications
- Create and disseminate tactical communication products to help leaders, hiring managers, and HR staff perform their tasks
- Disseminate communications plans to increase awareness and share critical information about the Cures Act and DHA
- Reinvigorate standing meetings between OTS and the Centers to improve effectiveness and encourage greater collaboration

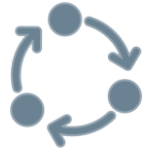
Note: Conclusions and recommendations are abbreviated for presentation purposes. The full versions can be found in the Interim Hiring and Retention Assessment Report.



RESULTS: CULTURE, COLLABORATION, AND COMMUNICATION

Similar to the Initial Assessment, stakeholders cited collaboration and communication challenges as major, ongoing hindrances to performing their roles in executing HR processes in an effective and efficient manner





RESULTS: RECRUITING AND HIRING PROCESSES

CONCLUSIONS

Conclusion 1

- FDA has been able to attract talent
- Lack of strategic recruiting and challenges with HR staff's capabilities impact the speed and quality of the process

Conclusion 2

- FDA new hires are qualified and able to perform well
- Process documentation is a persistent challenge, especially for classification

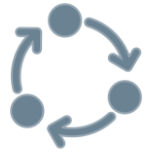
Conclusion 3

- FDA is realizing some process efficiencies via the Hiring Pilot, hiring and compensation flexibilities, and demonstrated use of shared certificates
- Approaches are not broadly and consistently implemented or measured

RECOMMENDATIONS

- Streamline frequently used hiring processes
- House the new hiring process maps in a centralized HR knowledge management repository
- Resolve the classification backlog
- Develop SOPs to standardize the classification process
- Document and regularly track outcome measures

Note: Conclusions and recommendations are abbreviated for presentation purposes. The full versions can be found in the Interim Hiring and Retention Assessment Report.



RESULTS: RECRUITING AND HIRING PROCESSES

The STRS Hiring Pilot data show some efficiencies. Initial assessment time-to-hire ranges were recorded from qualitative stakeholders interviews; whereas Hiring Pilot data are recorded, which is a positive step in tracking progress.

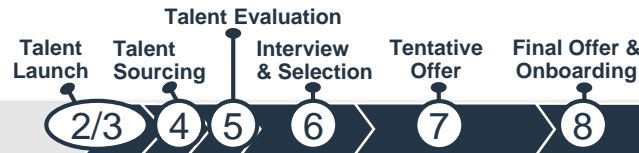
Traditional Title 5 Process (Initial Assessment)

22-300 Days

150-550 Days



Hiring Pilot (Interim Assessment)



22-87 Days

12-94 Days

using stand-alone certificates

using shared certificates

The Hiring Pilot was not designed to track or measure the Classification stage

Unknown process efficiency for the classification stage

Reduction in time-to-hire through Hiring Pilot

Demonstrated additional time-savings through use of shared certificates over stand-alone certificates

Over 60% faster than stand-alone certificates

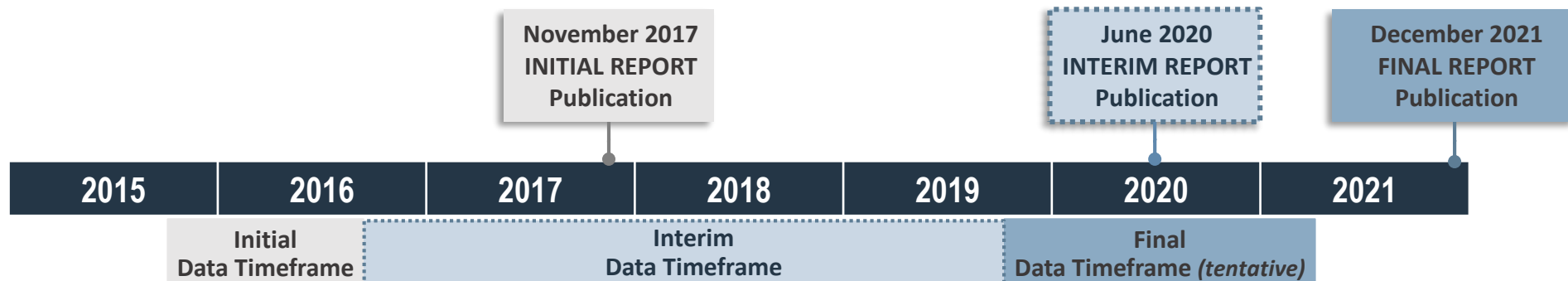
Eliminates Stages 2-5 in the hiring process

Saves between 15 and 53 days in end-to-end time-to-hire

Next Steps

NEXT STEPS

- General public provides comments through September 30, 2020
- FDA develops an implementation plan to move forward with Interim Report recommendations
- FDA prepares for the Final Assessment (to include improved data curation)
- A third-party evaluator conducts the Final Assessment, to be published in December 2021



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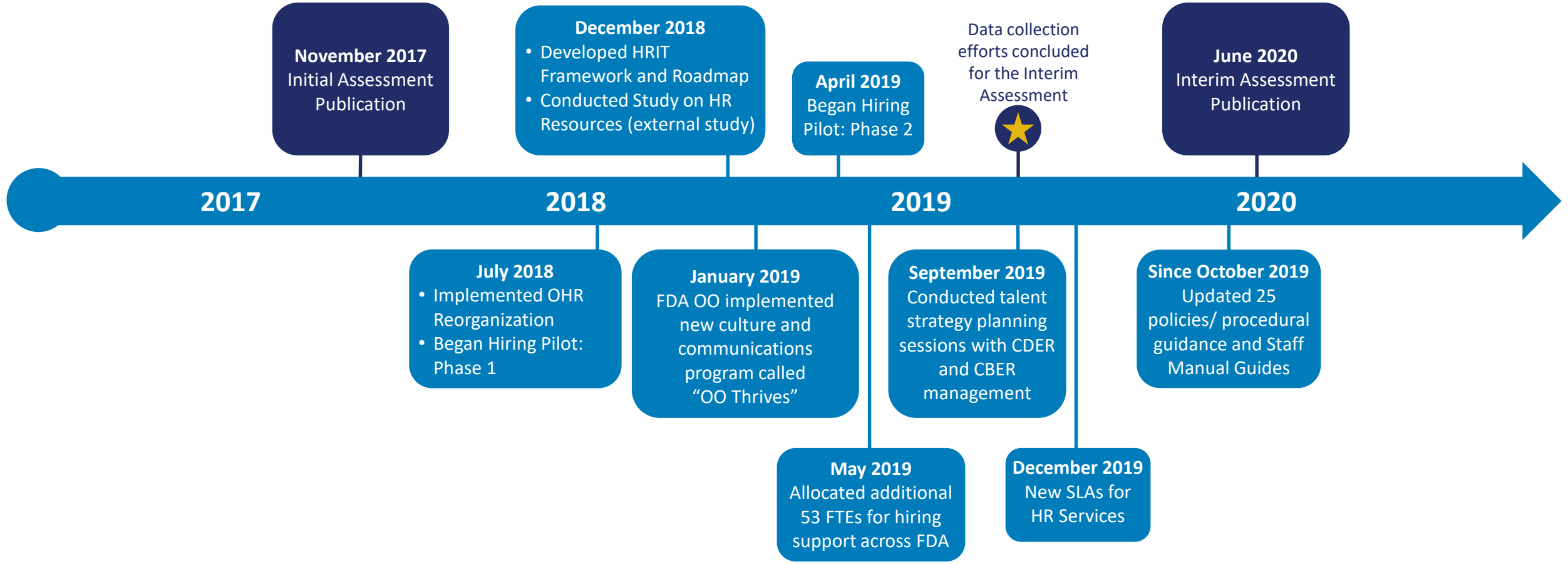
9:40 – 10:00 AM

MANAGEMENT'S RESPONSE TO THE FDA INTERIM HIRING AND RETENTION ASSESSMENT

Melanie Keller - Presenter
Director
Office of Talent Solutions

Tania Tse
Director
Office of Human Capital Management

FDA Recruiting, Hiring, and Retention - PROGRESS



FDA agrees the Agency lacks an enterprise-wide systems approach to integrate and optimize HR functions, and there is opportunity—in partnership with the Centers—to do so.

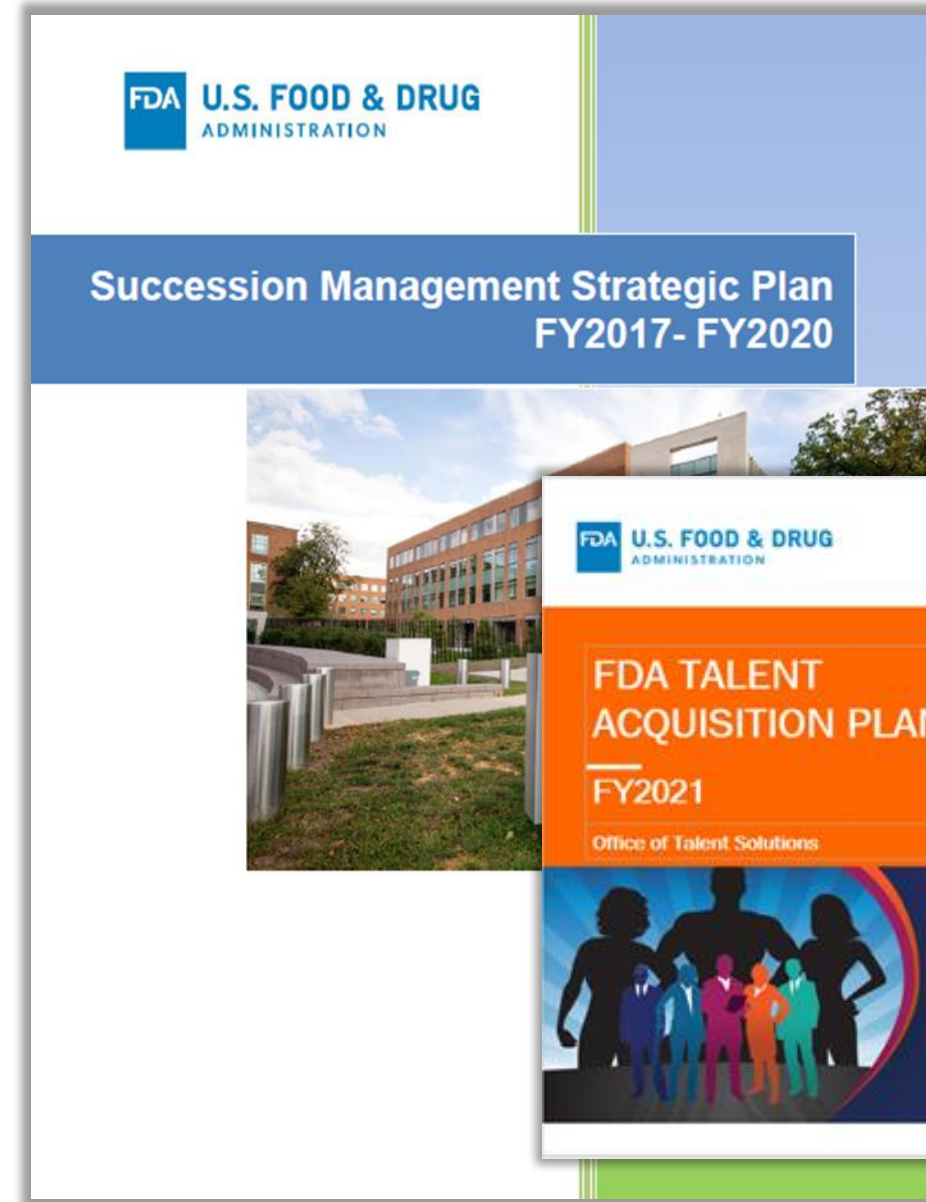
Response to Date

- ✓ CDER and CBER created Talent Strategy Plans
- ✓ OTS conducted initial talent strategy planning sessions with CDER and CBER management in September 2019
- ✓ OTS strengthened its classification program, and in FY20 Q2 achieved (for the first time) its KPI of 75% completed in <22 days
- ✓ CDER and CBER increased Cures hiring in FY20 by 200% over the same time period in FY19, with over 50% external recruitments

Strategy

Future Action Plans

- ❑ OTS will expand talent strategy planning sessions with CDER and CBER management
- ❑ OTS will refresh Talent Strategy Plans each fiscal year
- ❑ OHCM is renewing FDA's Succession Plan for 2021- 2023
- ❑ OHCM and the Enterprise Risk Management Team are conducting an FDA Retention Study
- ❑ OHCM is developing a Strategic Human Capital Plan to better integrate human capital functions



Data Management and Systems



FDA concurs with the report's conclusions regarding data measurement and integration and has developed an HRIT framework and roadmap to address such data challenges.

Response to Date

- ✓ FDA developed and implemented some Applicant Tracking Lifecycle and Analysis Solution (ATLAS) features as part of the current STRS Hiring Pilot
- ✓ OHCM developed an HRIT framework and roadmap
- ✓ FDA allocated funding to address necessary system improvements

Future Action Plans

- ❑ FDA developed and implemented some Applicant Tracking Lifecycle and Analysis Solution (ATLAS) features as part of the current STRS Hiring Pilot
- ❑ OHCM will continue to focus on FDA's HRIT framework and roadmap implementation
- ❑ FDA allocated funding to address necessary system improvements



Investments in existing system enhancements:

- Allow FDA to refine its data governance model
- Consolidate data sources into a single data repository
- Ensure proper remediation of data quality issues
- Automate the hiring process
- Integrate external application

Benefits of ATLAS and e-Portal Systems:

- Address data short-comings
- Provide data governance
- Provide real-time integrated data
- Provide report building capability

HR Staff Capability and Capacity



FDA reorganized its Office of Human Resources' functions into two separate offices in 2018 to improve service delivery and provide enhanced dedicated leadership; impacts have begun to show positive results.

Response to Date

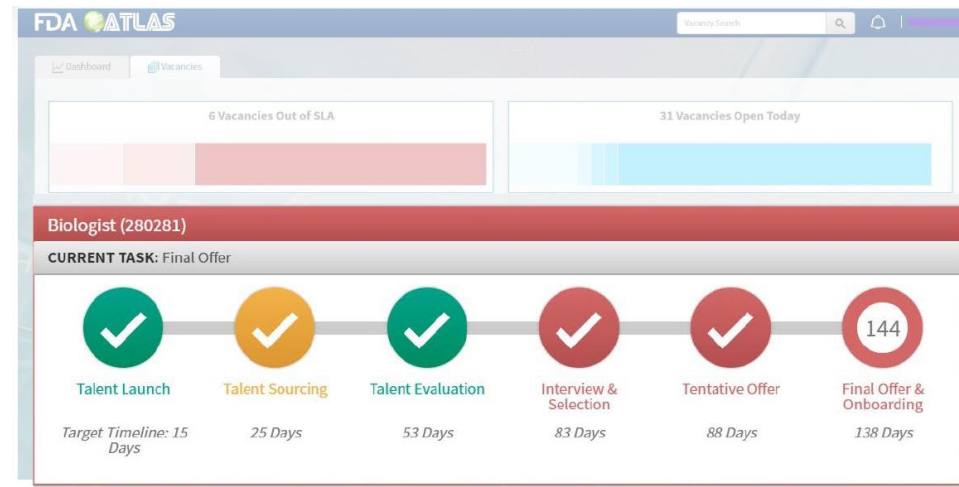
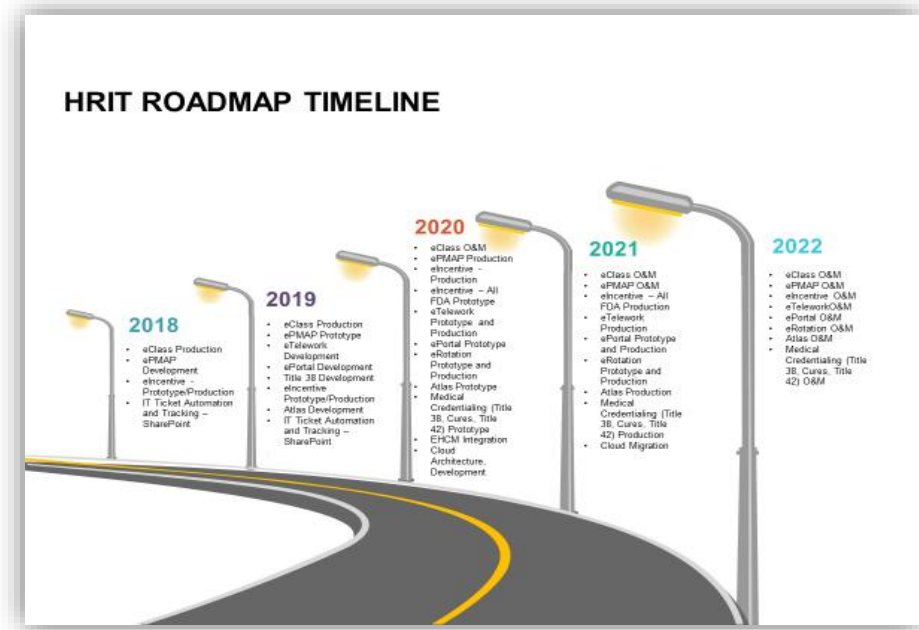
- ✓ FDA reorganized its HR functions into two separate offices in 2018 to improve service delivery and provide enhanced dedicated leadership
- ✓ OTS had an independent resource study conducted in 2018, which found that OTS lacked the necessary resources to perform hiring work
- ✓ FDA allocated 53 additional FTEs for hiring support as of FY20
- ✓ OTS provided dedicated HR resources to the CDER and CBER hiring pilot
- ✓ FDA implemented new Talent Academy training requirements as a performance metric for HR staff
- ✓ FDA has newly implemented Service Level Agreements for HR services to improve transparency and accountability of delivery of services

HR Staff Capability and Capacity



Future Action Plans

- ❑ FDA will continue to collaborate and enhance the quality, quantity and transparency of its services with enterprise solutions reflected in the HRIT Roadmap, pending investment
- ❑ FDA's implementation of ATLAS will enable FDA to track HR workload, manage distribution of work, and proactively manage talent plans and results



FDA agrees more robust process documentation and guidance will help enhance its hiring processes, and plans to communicate more of what is working well and leverage best practices across the Agency.

Response to Date

- ✓ OTS and OHCM leadership now communicate with FDA hiring managers on a regular basis
- ✓ OTS and OHCM HR staff conduct regular recurring meetings with Center staff to review HR activities, remove barriers, and ensure accountability
- ✓ FDA updated 25 policies/guidance and Staff Manual Guides since 9/30/19
- ✓ FDA implemented the HR Policy Work Group to promote transparency
- ✓ FDA awarded an Inter-Agency Agreement (IAA) with OPM to improve and optimize its Title 5 Classification Program
- ✓ FDA Office of Operations (OO) implemented a new culture and communications program called “OO Thrives”
- ✓ OTS now provides training and guidance to stakeholders highlighting the Special Placement Programs

Future Action Plans

- ❑ FDA plans to communicate what works well and leverage best practices across the Agency
- ❑ FDA will develop a plan to remediate Title 5 Classification issues and instill a long-term standardized operation plan by 9/1/2020 working with the Office of Personnel Management (OPM)
- ❑ FDA will implement a robust internal communication campaign to orient CDER and CBER on Title 21 (21st Century Cures hiring) efforts



Recruiting and Hiring Processes



FDA agrees it needs to continue improving the efficiency and effectiveness of its processes through better documentation, training, and communications.

Response to Date

- ✓ FDA has completed two Phases of the FDA Hiring Pilot resulting in an average 60% reduction in time to hire
- ✓ OTS has implemented talent strategy sessions with Centers to maximize the appropriate use of the 9 different authorities available to support hiring

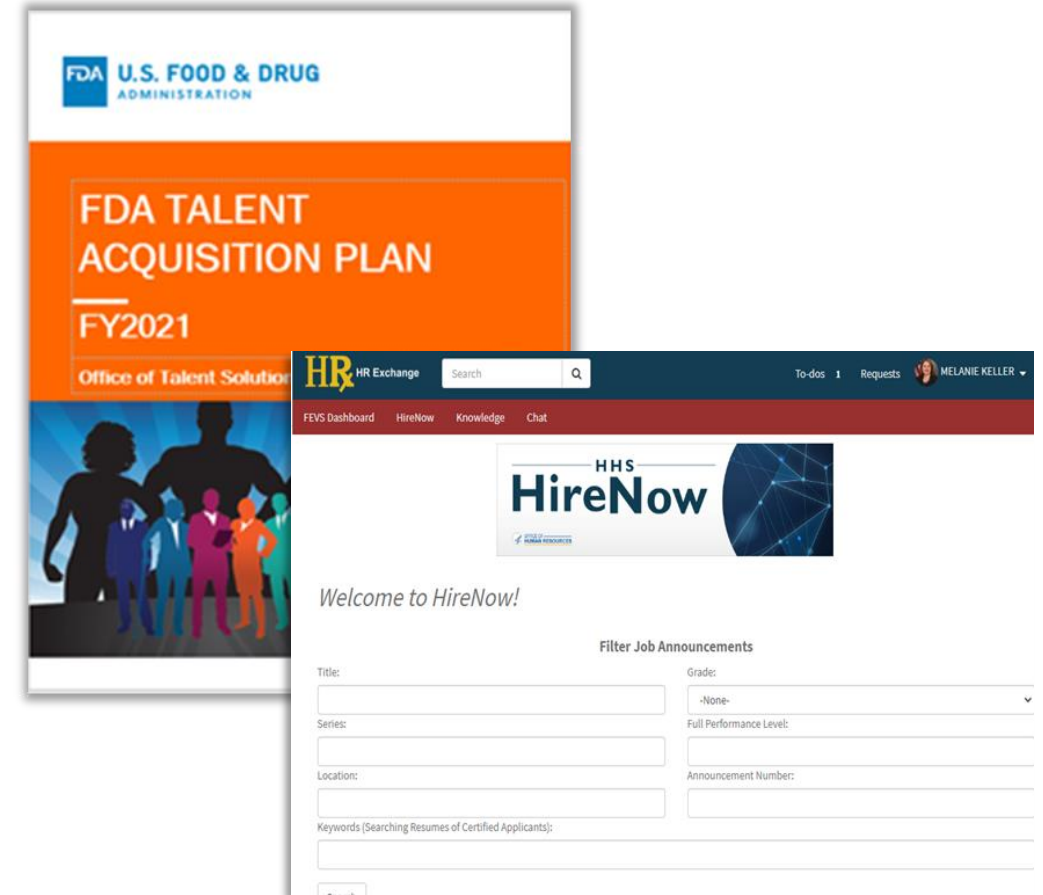


Recruiting and Hiring Processes



Future Action Plans

- ❑ FDA will implement and complete Phase III of the FDA Hiring Pilot
- ❑ FDA will implement the *HHS Hire Now* system by July 2020 to increase access to a broader pool of candidates
- ❑ OTS will conduct a refresh of Center Talent Plans by 9/30/2020 to create an FDA Talent Strategy
- ❑ FDA will deploy the Applicant Tracking Lifecycle and Analysis Solution (ATLAS) Agency-wide
- ❑ FDA will analyze the best practice hiring capacity and capabilities of the STRS Hiring Pilot and expand them Agency-wide





10:00 – 11:00 AM

OPEN PUBLIC COMMENT

Ema Kamara

Director [Acting]

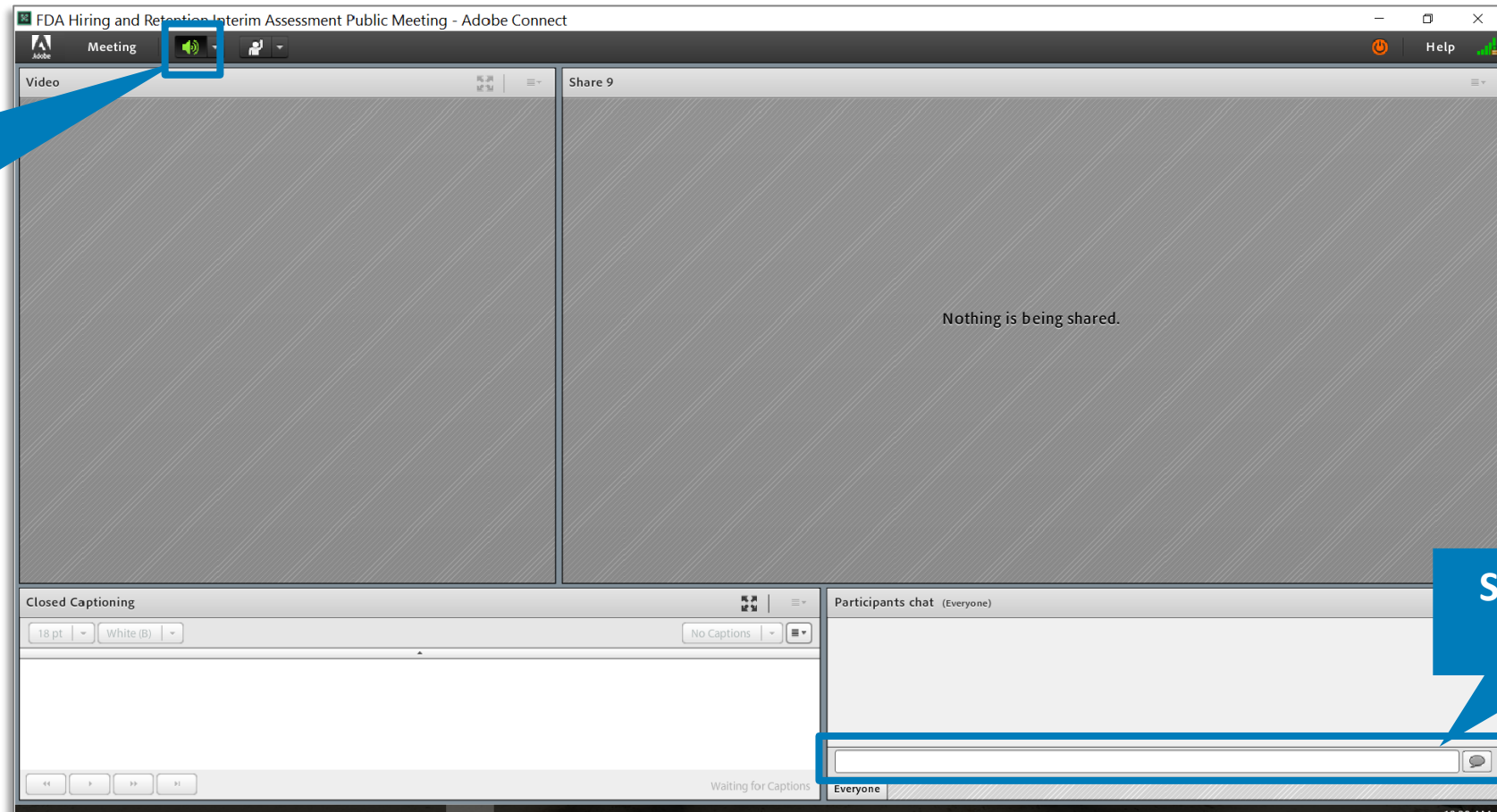
Office of Planning and Evaluation | Office of Operations

How to Submit Questions at the End of the Meeting



- Submit your questions at the end of the presentation via the Adobe chat box
Please use the following format: *Name, Organization: Comment*
- Questions/comments will be recorded as part of the meeting transcript for public record

To hear audio,
make sure your
audio icon is
green 



Submit your
questions

How to Submit Comments on the Public Docket

Comments can also be submitted through September 30, 2020 via the public docket at <https://www.regulations.gov/document?D=FDA-2020-N-1500-0001> or by searching “Hiring and Retention Interim Assessment” at www.regulations.gov

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Hiring and Retention Interim Assessment

N Food and Drug Administration Hiring and Retention Interim Assessment; Public Meeting; Request for Comments

This Notice document was issued by the **Food and Drug Administration (FDA)**
For related information, [Open Docket Folder](#)

Action
Notice of public meeting; request for comments.

Summary
The Food and Drug Administration (FDA, the Agency, or we) is holding a virtual meeting entitled “FDA Hiring and Retention Interim Assessment” and an opportunity for public comment. The topic to be discussed is FDA’s hiring and retention interim assessment which was an independent assessment performed by Booz Allen Hamilton, published on June 5, 2020. This public meeting will take place virtually due to extenuating circumstances and will be held by webcast only.

Dates
The public meeting will be held on July 30, 2020, from 9 a.m. to noon. Submit either electronic or written comments on this public meeting by September 30, 2020. See the SUPPLEMENTARY INFORMATION section for registration date and information.

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