



Public Meeting on the FDA Final Hiring and Retention Assessment

Public Meeting
March 15, 2022
9:00 AM – 10:30 AM

A photograph of three scientists in a laboratory. A woman in a blue hijab and white lab coat is smiling and looking up at a man in a white lab coat who is pointing at a tablet. Another woman in a white lab coat is standing to the right, also smiling and pointing at the tablet. In the background, there is a microscope and other lab equipment.

WELCOME AND INTRODUCTION

9:00 AM – 9:05 AM

Yashika Rahaman, Ph.D.

Director

Office of Planning, Evaluation, and Risk Management | Office of Operations

Agenda



Topic	Presenter	Time
Welcome and Background	Yashika Rahaman, Ph.D. Director Office of Planning, Evaluation, and Risk Management Office of Operations	9:00 AM – 9:05 AM
Final Assessment Presentation	Kristen Stanton and Dena Papazoglou Talent Transformation Center of Excellence Booz Allen	9:05 AM – 9:40 AM
FDA Response to Final Assessment	Melanie Keller Director Office of Talent Solutions Office of Operations	9:40 AM – 10:00 AM
Q&A / Open Public Comment	Yashika Rahaman, Ph.D. Director Office of Planning, Evaluation, and Risk Management Office of Operations	10:00 AM – 10:30 AM

Background and Scope

Overview

Through its User Fee Agreements, FDA is authorized to collect fees from sponsors and applicants to help expedite the development, review, and approval processes of human drugs and biologics.

Scope

As part of PDUFA VI and BsUFA II agreements, FDA committed to a series of three assessments of the recruiting, hiring, and retention of its human drug and biologics review program staff (i.e., CDER and CBER)



User Fee Commitments



The **Prescription Drug User Fee Act (PDUFA)** was first created by Congress in 1992 and authorizes FDA to collect fees from companies that produce certain human drug and biological products. Since the passage of PDUFA, user fees have played an important role in expediting the drug approval process.



The **Biosimilar User Fee Act (BsUFA)** was first created by Congress in 2012 and authorizes FDA to collect fees from biosimilar developers to help fund the process for the review of biosimilar biological product applications.

Final Hiring and Retention Assessment

9:05am – 9:40am

Kristen Stanton and Dena Papazoglou
Booz Allen Hamilton



ORGANIZATIONAL CHALLENGES IMPACTING FDA TALENT

A confluence of internal and external factors impact the Agency's ability to attract, hire, and retain talented human drug and biologics review program staff.



**Most Competitive
Market for Talent
in Decades**



**Complex Hiring
and Pay
Authorities**



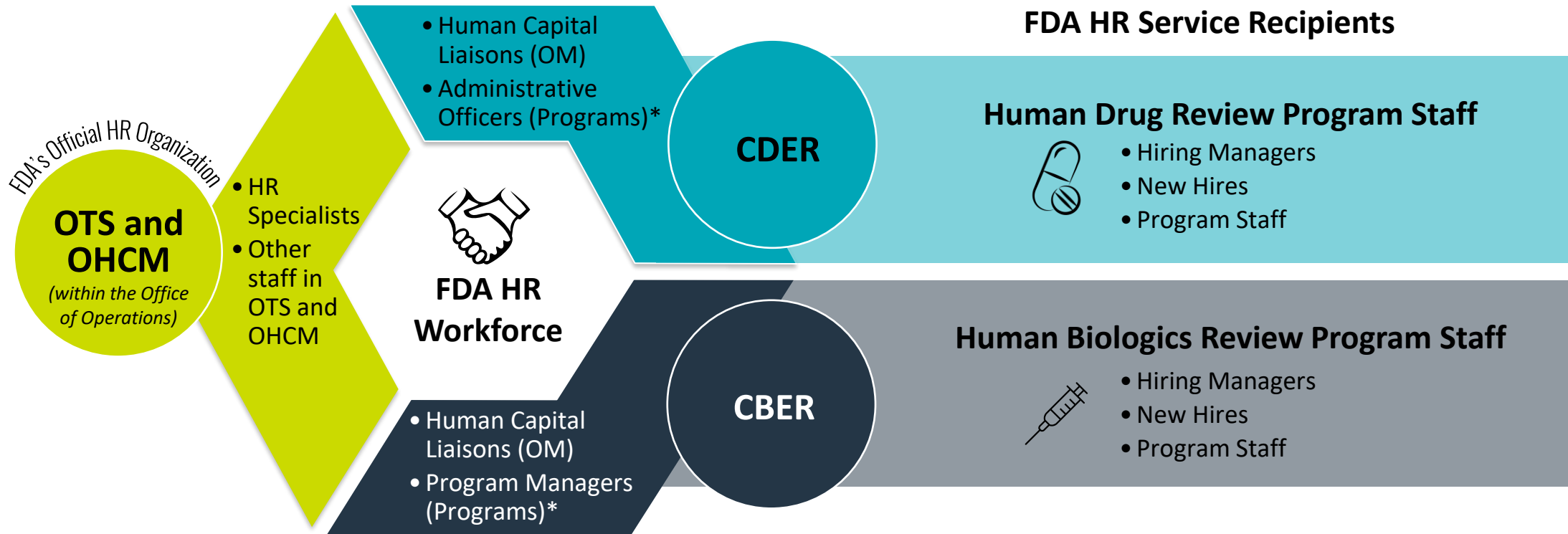
**Workforce
Changes Due to
COVID-19**



**Risk of Higher
Turnover from
Increased Retirements
and Desire for
Continued Telework**

FDA HR WORKFORCE AND SERVICE RECIPIENTS

A decentralized HR workforce fuels complexity in processes and impacts how HR service recipients view the quality of customer service provided.

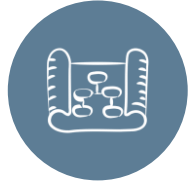


*also perform administrative duties other than HR support

ASSESSMENT METHODOLOGY

Booz Allen used a 4-step methodology that integrates multiple methods and perspectives to corroborate a variety of evidence and gain a well-rounded understanding of HR functions at FDA.

1. Plan Assessment



Five Assessment Categories

- Strategy
- Culture, Collaboration, and Communication
- Recruiting and Hiring Processes
- Data Management and Systems
- HR Staff Capability and Capacity

2. Capture Data



Multi-Method Data Collection Approach

- 2 Data Calls
- 3 Center and HR Workforce Surveys
- 22 Leadership Interviews
- 24 HR Stakeholder Focus Groups
- 50+ FDA Data Files
- 135+ Organization Documents

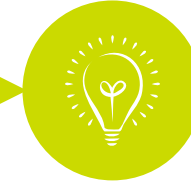
3. Analyze Data



Integrated Data Driven Results

- 20 Findings
- 9 Conclusions
- 10 Recommendations

4. Synthesize Results



Key Takeaways

KEY ASSESSMENT TAKEAWAY

FDA revitalized many aspects of recruiting, hiring, and retention, in keeping with User Fee commitments; progress achieved by separate organizations must be embraced Agency-wide for true transformation.

1 Initial-to-Interim

FDA focused on improving hiring timeliness and quality, and laid the groundwork to enhance effectiveness of recruiting and retention.

2 Interim-to-Final

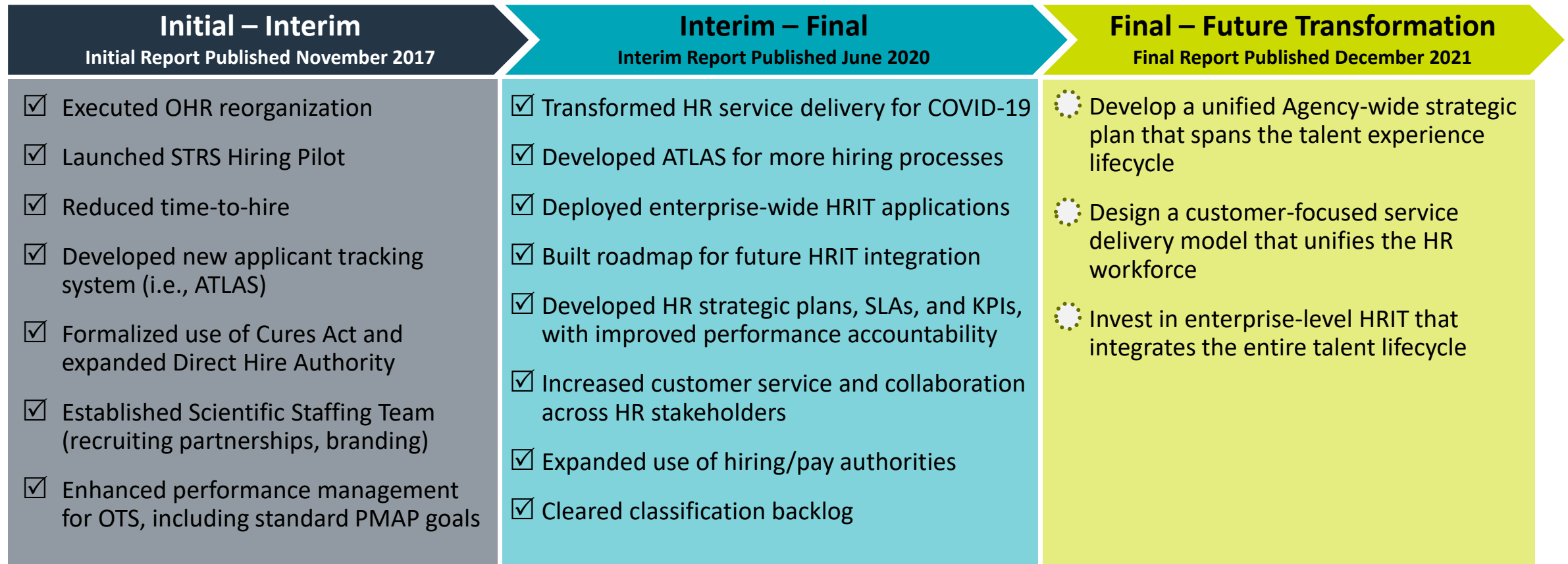
OTS, OHCM, CDER, and CBER continued maturing and formalizing improvement efforts, with measurable—albeit limited—results across all HR functions.

3 Final-to-Transformational Change

FDA must apply unified enterprise-wide coordination, influence, and investment to address systemic HR challenges.

PROGRESS OVER TIME

FDA investments have produced improvements; embracing a unified enterprise-wide approach is needed for true transformation going forward.



Results and Recommendations

RESULTS AND RECOMMENDATIONS

This section presents overarching, cross-cutting themes and recommendations that apply across the assessment, as well as results and recommendations by specific assessment category.

	Cross-cutting Themes	Data-driven Results	Actionable Recommendations	
		<i>Category-specific</i>	<i>Cross-cutting</i>	<i>Category-specific</i>
Strategy		✓		✓
Culture, Collaboration, and Communication		✓		✓
Recruiting and Hiring Processes		✓		✓
Data Management and Systems		✓		✓
HR Staff Capability and Capacity		✓		✓

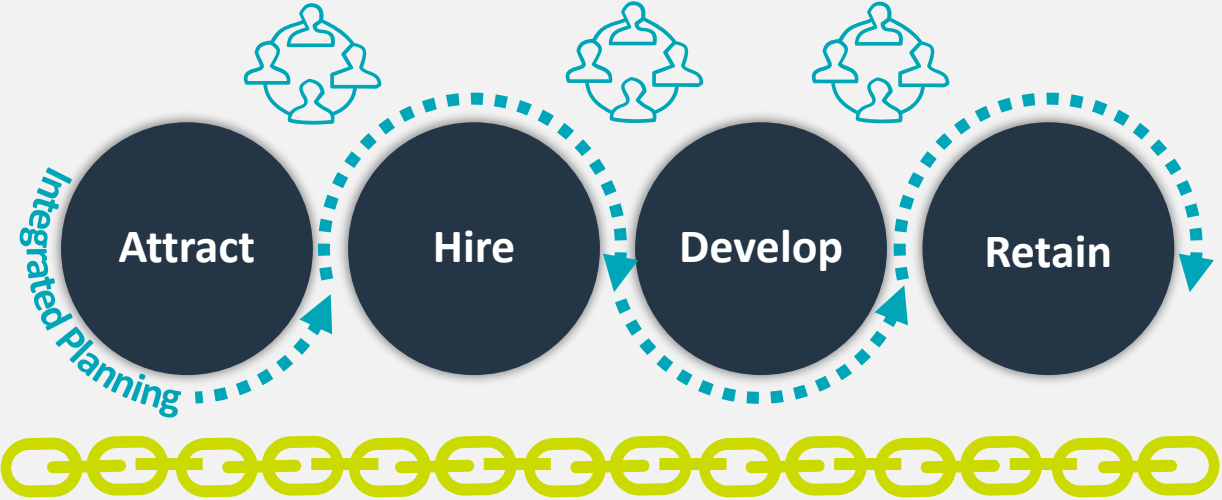
CROSS-CUTTING THEMES FOR TRANSFORMATIONAL CHANGE

The assessment surfaced three cross-cutting themes about FDA’s need for enterprise-level solutions.

Cross-cutting HR Challenges Need Enterprise-level Solutions

Enterprise-level Solutions

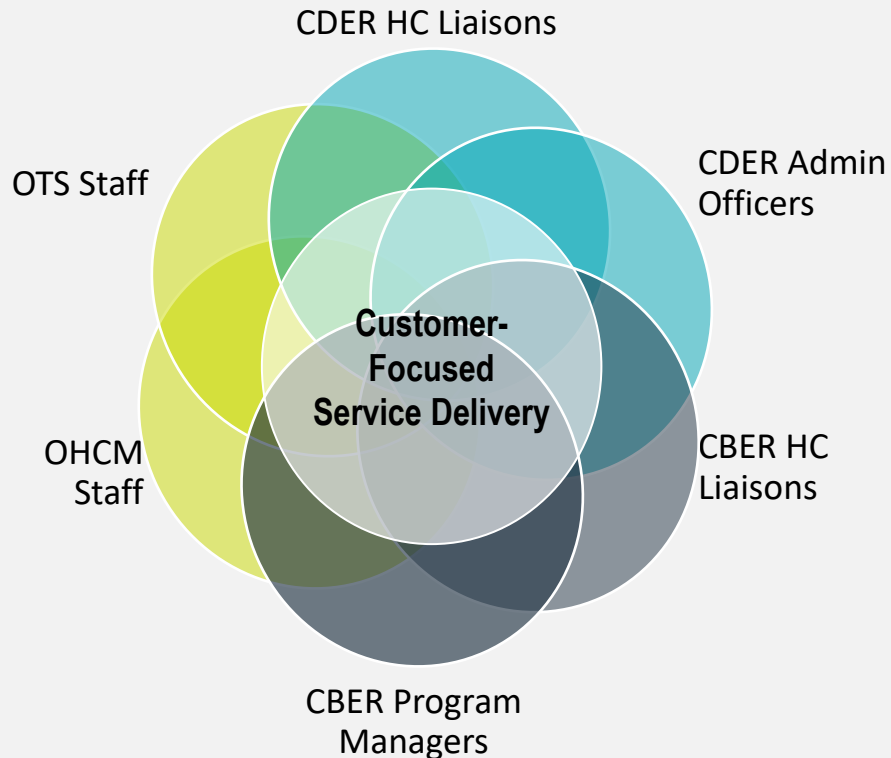
- A clear and consistent HR service model that balances a strategic business partner role with a customer-focused mindset
- An Integrated Talent Experience Lifecycle that incorporates both HR services and Center-based management, with a focus on the employee or user perspective
- An integrated HRIT system and tools to support the end-to-end talent experience and achieve strategic talent outcomes



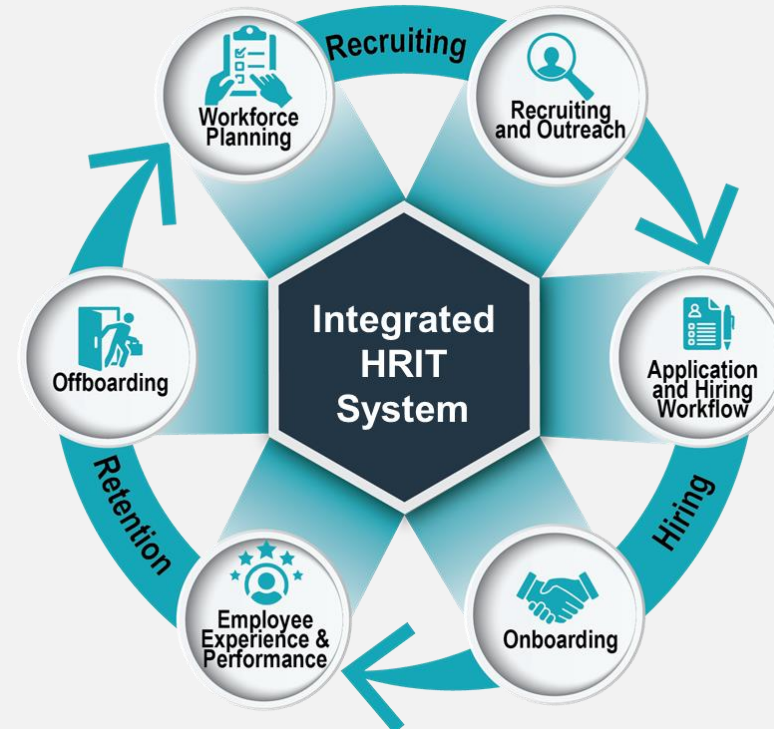
RECOMMENDATIONS | CROSS-CUTTING

Two cross-cutting recommendations call for enterprise-level solutions to systemic challenges across all five assessment categories, anchored by category-specific results and recommendations.

Integrated HR Service Model



Enterprise HRIT System

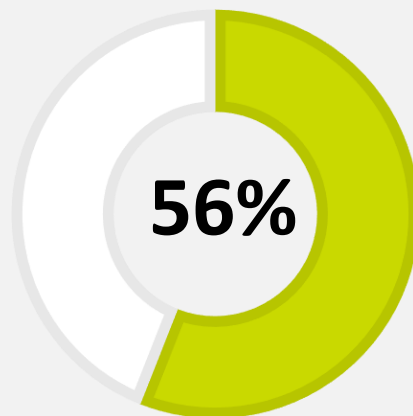


RESULTS | STRATEGY

Survey results from CDER and CBER Staff, HR Managers, and HR Staff indicate that COVID-19 deeply impacted recruiting, hiring, and retention in both positive and negative ways.

Impact of COVID-19 on Recruiting, Hiring, and Retention

Over half of all survey respondents report a **moderate to high impact**



Positive



- Stability of federal employment
- Pride in FDA's mission
- New recruiting techniques and retention incentives

Mixed



- More telework was valuable
- Possible turnover when telework flexibility changes

Negative



- Increased workload
- Risk of burnout

RECOMMENDATIONS | STRATEGY

Commit to developing and institutionalizing an enterprise-wide, strategic HR service delivery model, HRIT system, and retention strategies that integrate the entire talent lifecycle.

Refine Retention Strategies

- Build on popularity of work flexibilities, such as telework
- Improve coordination and consistency across CDER and CBER related to use of incentives
- Establish retention targets and use strategies most effective for those groups, such as
- Address succession needs proactively



Cross-Cutting



Enterprise HRIT System



Integrated HR Service Model

RESULTS | CULTURE, COLLABORATION, AND COMMUNICATION

Customer satisfaction measurably increased, but overall satisfaction remains low. OTS and OHCM improved communication and collaboration, but CDER and CBER still cited ongoing challenges with HR.

OTS and OHCM have increased communication and collaboration with CDER and CBER

- ✓ Led consultative HR discussions
- ✓ Added **19** SOPs and process documents
- ✓ Increased accountability by tracking KPIs
KPIs met: 100% OHCM; 63% OTS

More customers and providers are satisfied with recruiting and hiring

- Moderate or significant improvement** in satisfaction due to OTS and OHCM support
- Change in Interim to Final Survey percentages:*
- ✓ CDER/CBER Hiring Managers, **+18 points**
 - ✓ HR Workforce, **+31 points**



CDER and CBER still need...

- More engagement with OTS/OHCM
- More documented process guidance
- Hiring process checklists and job aids

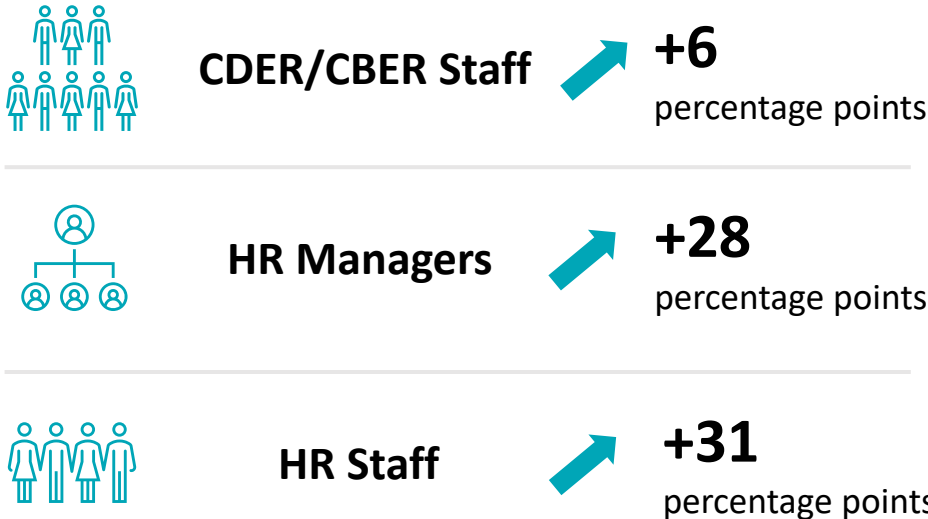
Overall customer satisfaction with recruiting and hiring is still low...

- Little or no improvement** in satisfaction due to OTS and OHCM support
- Final Survey results:*
- CDER/CBER Hiring Managers, **69%**

RESULTS | CULTURE, COLLABORATION, AND COMMUNICATION

HR processes are meeting the needs of more stakeholders; since the Interim Assessment, more HR staff said that handoffs are effective across all process steps, while managers of HR staff had varying views.

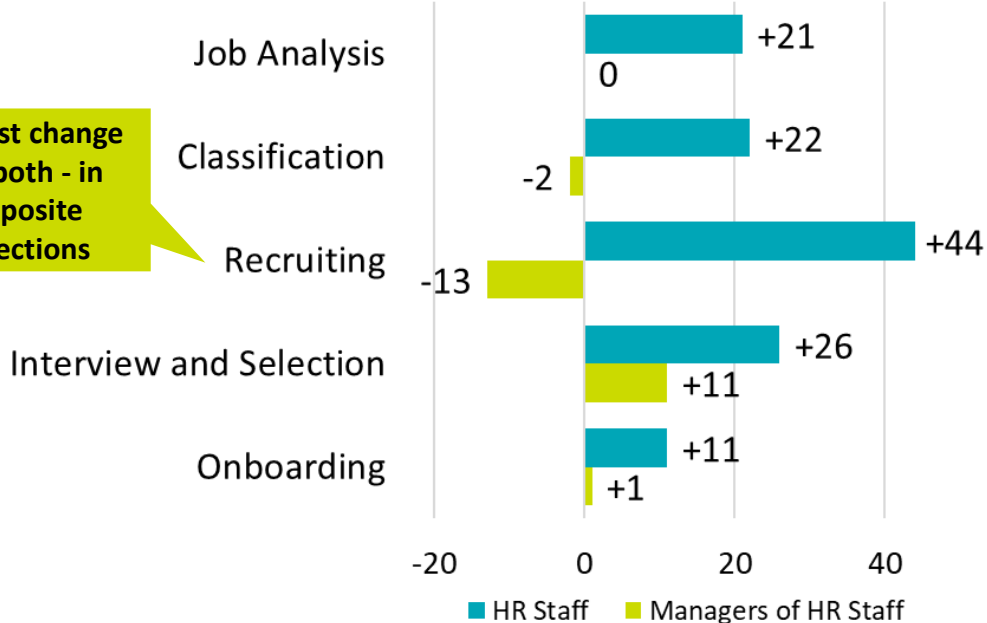
Increase in percentage of stakeholders who agree that HR functions meet FDA's needs



Changes in percentage of the HR Workforce who agree that process handoffs are effective

- Notable increase for HR staff across all process steps
- Relatively little change for Managers of HR Staff

Biggest change for both - in opposite directions



RECOMMENDATIONS | CULTURE, COLLABORATION, AND COMMUNICATION

Engage with stakeholders across organizations to cultivate adoption of a standardized service delivery model and engagement strategy that address customer needs and build a culture of trust and respect.

Develop a stakeholder engagement strategy to encourage two-way communication

- Clarity on customer requirements
- Managed expectations for HR services
- More transparency and trust-building



TWO-WAY COMMUNICATION

Cross-Cutting

Integrated HR Service Model

RESULTS | RECRUITING PROCESS

FDA attracts qualified candidates and has advanced its strategic outreach efforts; better process coordination, guidance, and data integration across HR functions will increase recruiting effectiveness.

Recruiting Accomplishments Since Interim Assessment

- ✓ OTS established **53** new external strategic partnerships
- ✓ Average **23% increase** in online activity
- ✓ CDER and CBER **formalized** recruiting practices
- ✓ Quick pivot to **virtual recruiting practices** in response to COVID-19
- ✓ More **coordinated approach** to candidate outreach

Centers attended **78%** of OTS-scheduled events

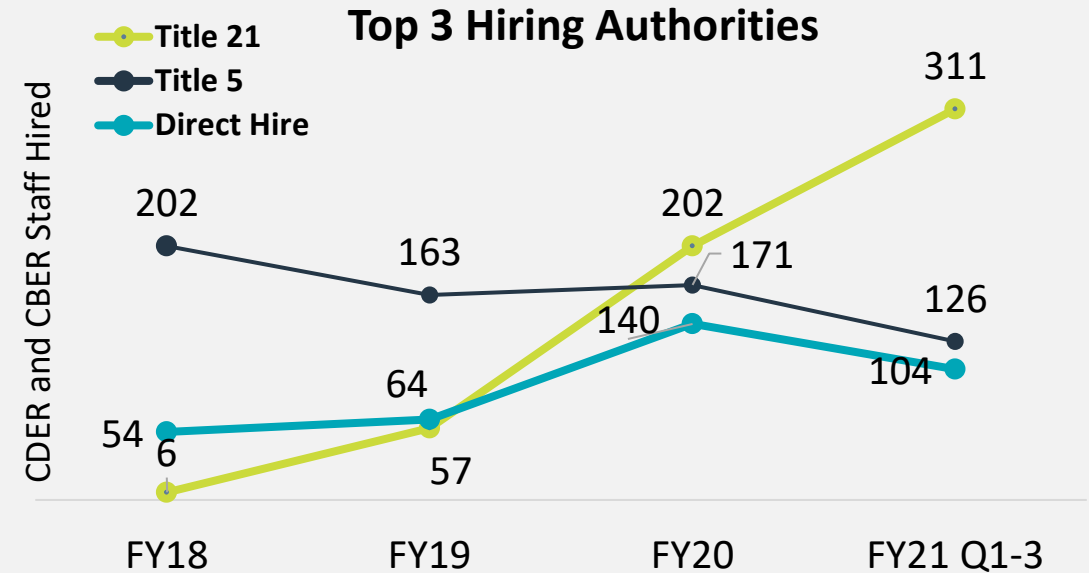
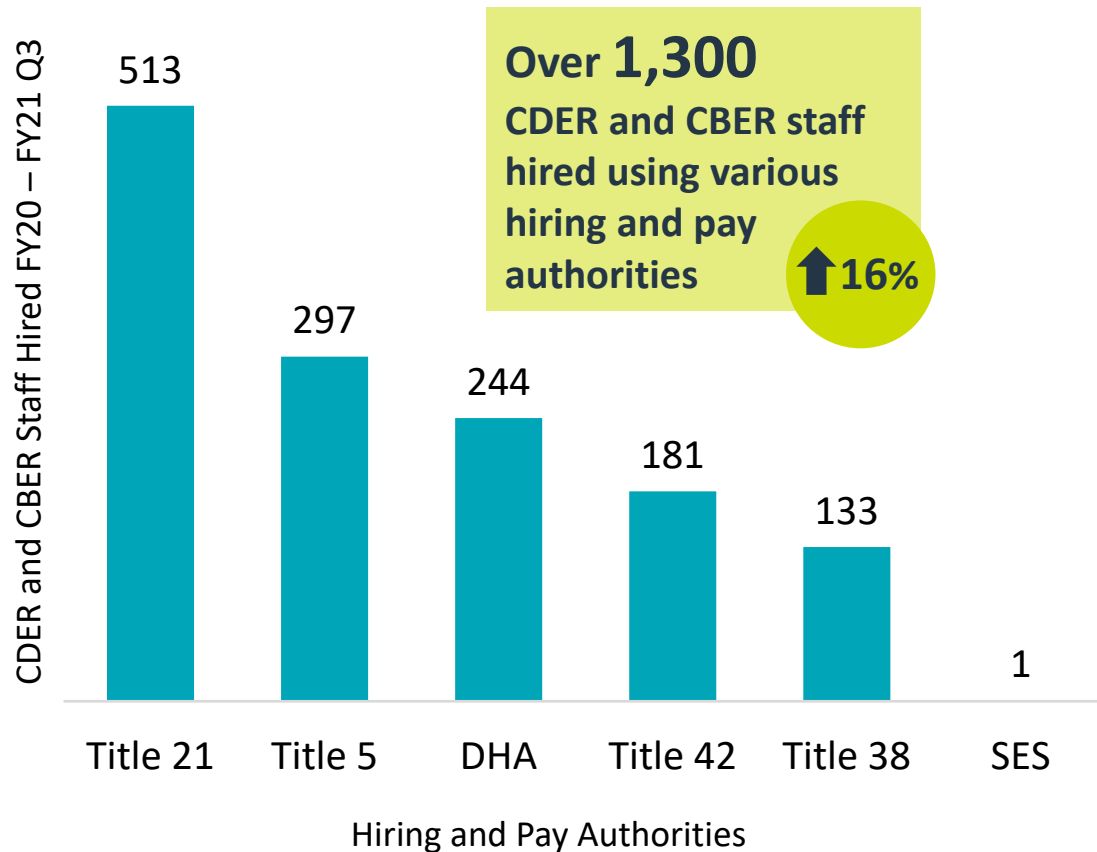
Identified Opportunities to Improve Recruiting

- ⊙ Target outreach efforts
- ⊙ Measure and monitor recruiting effectiveness
- ⊙ Continue to diversify candidate pool
- ⊙ Link recruiting data with hiring



RESULTS | HIRING PROCESSES

CDER and CBER have effectively filled vacancies using selective hiring authorities to address surges in critical hiring needs.

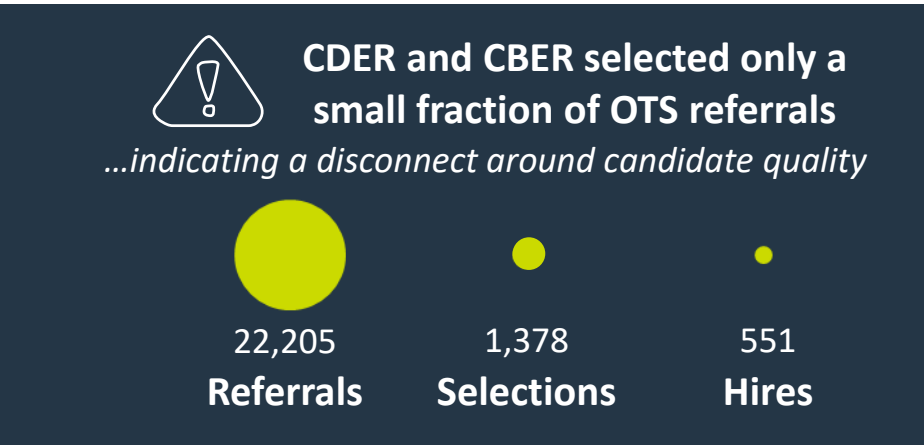


Stakeholders report several benefits of Title 21 and DHA

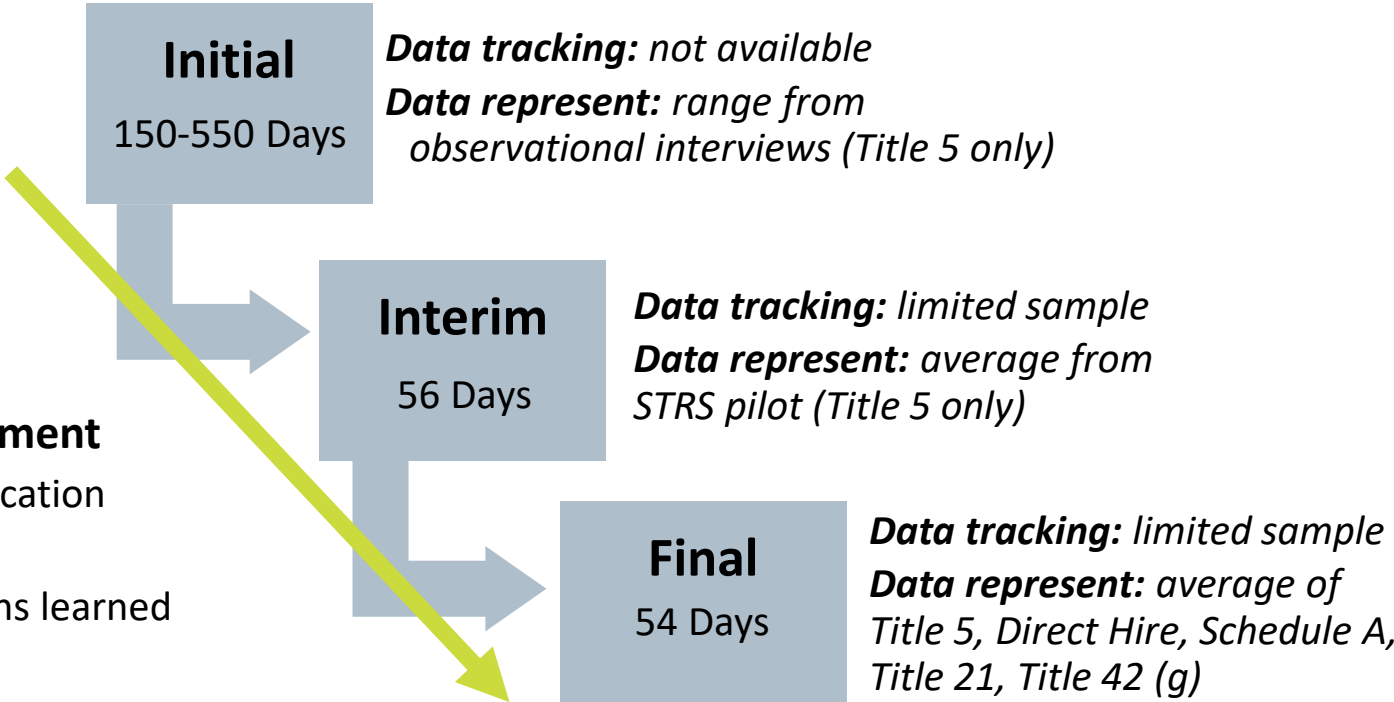
- ✓ Perceived as faster than the traditional Title 5 process
- ✓ Allow more competitive salaries
- ✓ DHA enables more one-on-one connections with candidates

RESULTS | HIRING PROCESSES

Process improvements and targeted use of hiring authorities have helped support critical CDER and CBER hiring needs, but further maturity in process coordination, guidance, and data tracking is necessary.



FDA achieved **faster** average hiring timeframes in Interim and Final



Hiring Successes Since the Initial Assessment

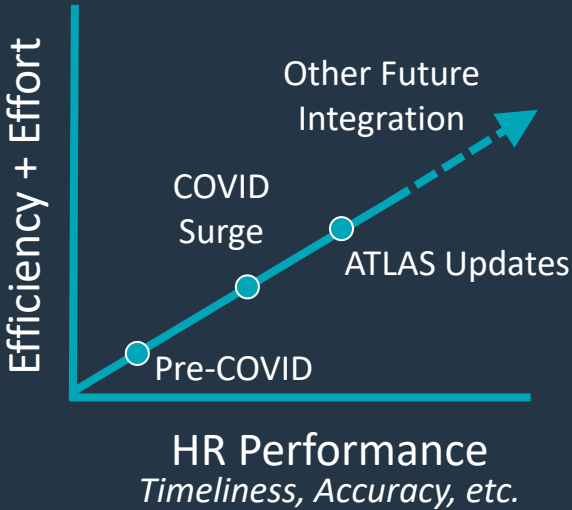
- ✓ Reduced processing time, including classification
- ✓ Cleared the Classification backlog
- ✓ Applied process improvements from lessons learned
- ✓ Adopted accountability measures
- ✓ Improved workflow tracking by hiring authority

RECOMMENDATIONS | RECRUITING AND HIRING PROCESSES

Integrate the full talent lifecycle to improve workflow and customer experience; refine metrics to sustain improved surge performance; examine the disconnect between qualified candidate referrals and selections.

Evolve metrics as efficiencies are gained
(e.g., COVID, system integrations)

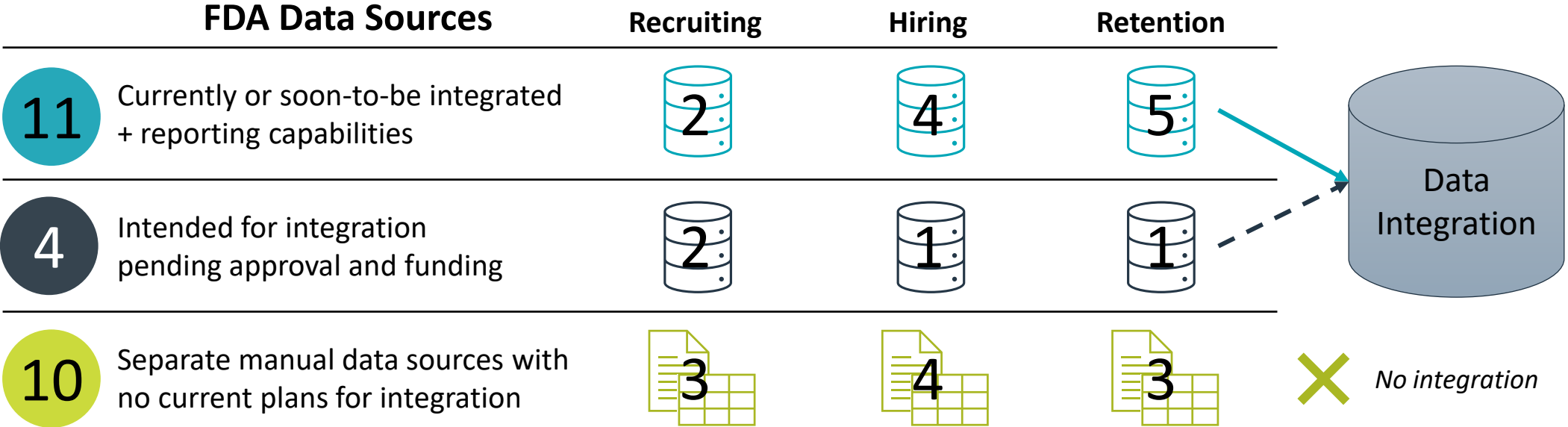
Examine the disconnect with low selections
from qualified candidate referrals



RESULTS | DATA MANAGEMENT AND SYSTEMS

FDA has planned and funded HRIT to improve HR process workflows and transparency, but current plans do not utilize the full range of available system capabilities to integrate the entire talent lifecycle.

Data from 11 different data sources will soon be integrated in a common HRIT platform; FDA needs additional investment and planning to integrate remaining systems and manually-tracked data sources to support end-to-end HR processes.

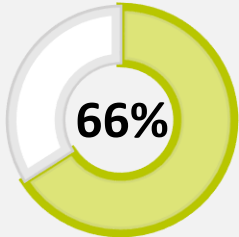


RESULTS | DATA MANAGEMENT AND SYSTEMS

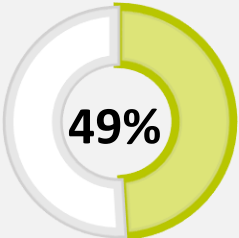
Stakeholder feedback consistently conveys the need for a fully integrated HRIT system.

SURVEYS

“A reliable, transparent HRIT system would make HR processes more successful.”



CDER and CBER Staff



HR Workforce

INTERVIEWS AND FOCUS GROUPS

Composite of Participants' Feedback

“Using non-integrated HRIT systems hinders HR work in several ways.”

- Duplicative efforts
- Less transparency
- More errors
- Time-consuming, manual processes

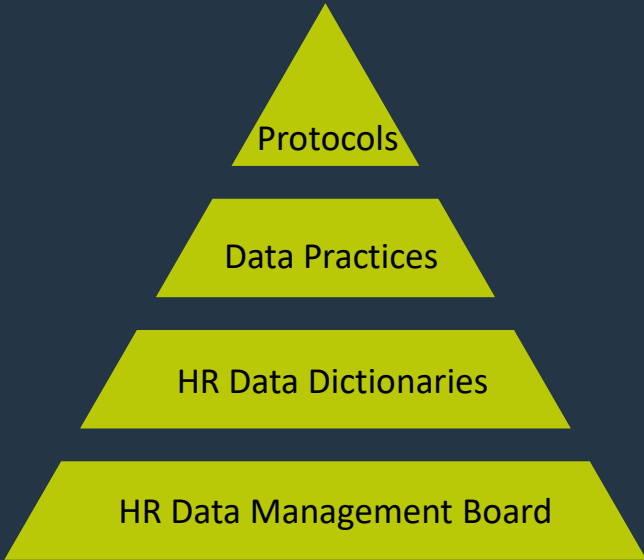
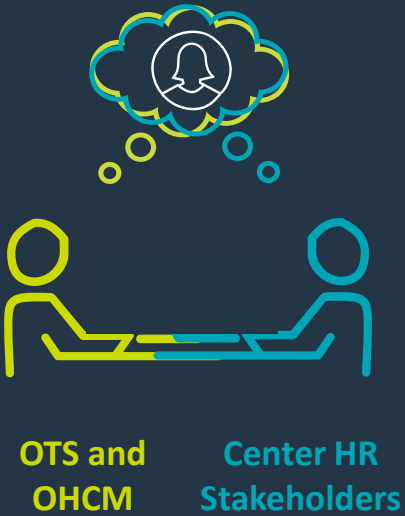
“An agency-wide approach and investment is necessary (e.g., buying or building a system).”

RECOMMENDATIONS | DATA MANAGEMENT AND SYSTEMS

Establish an enterprise HRIT system that leverages integrated data to support automation and analytics; encourage stakeholder adoption and infuse greater structure in data management and reporting practices.

Encourage two-way communication to increase awareness and user adoption

Continue to build and infuse more uniformity and structure to data management



RESULTS | HR STAFF CAPABILITY

FDA has improved HR capability with expanded OTS professional development initiatives, improved competency ratings, and increased hiring manager satisfaction on abilities of staff performing HR work.

Capability-Building Initiatives

- ✓ OTS Team Development Assessment and Engagement
- ✓ OTS Leadership Assessment and Coaching
- ✓ OTS Competency Framework
- ✓ CBER Human Capital Resource Hub



Increased Proficiency and Satisfaction Ratings

Manager ratings of HR Staff technical competencies

Recruitment +33

Federal HR Knowledge +18

Hiring Manager satisfaction in HR Specialist abilities

Applying Knowledge of HR +14

Meeting Timelines and Commitments +12

RESULTS | HR STAFF CAPACITY

FDA's HR servicing ratio has not changed; CDER and CBER invest heavily in dedicated HR resources to supplement OTS and OHCM staff in the Agency's HR organization.

FDA's HR Servicing Ratio is **1:59** and is comparable to HR Servicing Ratio benchmarks



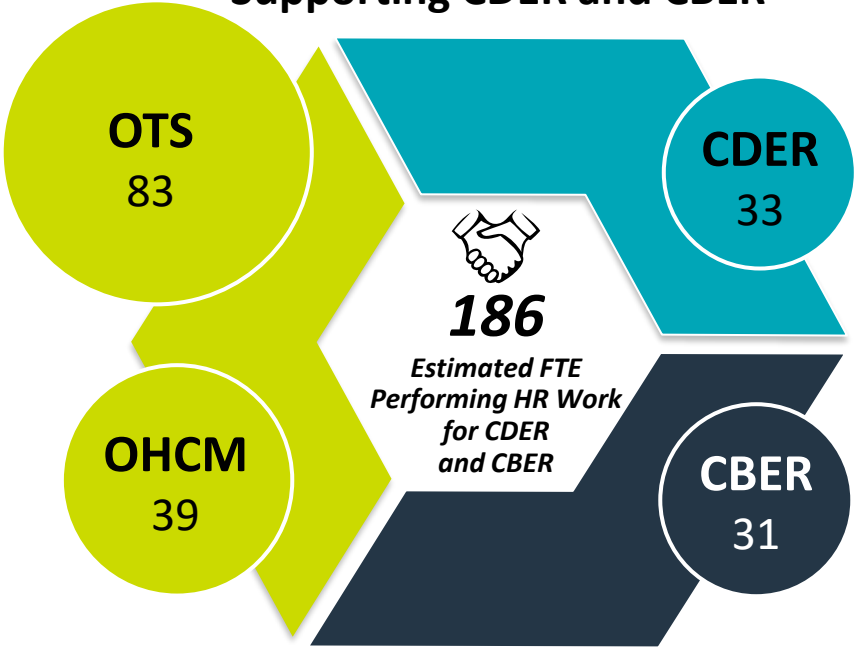
321

HR Specialists
in OTS and OHCM

18,902

FDA Employees

FDA HR Workforce Supporting CDER and CBER*



**Post-publication clarifications were made by CBER on the count of their staff supporting HR activities. In addition, CBER and CDER results shown here now reflect the FTE devoted to HR work (a proportion of staff workload), rather than the number of staff. An addendum to the published report is forthcoming.*

RECOMMENDATIONS | HR STAFF CAPABILITY AND CAPACITY

Align resources and refine workload management for customer-focused service delivery; shift to a unified competency model across the HR workforce; standardize performance goals and accountability.



Refine workload distribution and management using workflow metrics



Establish a unified competency model across the HR workforce



Hold managers of HR staff accountable for reinforcing HR performance standards

Cross-Cutting



Integrated HR Service Model

Close Out



NEXT STEPS



March 15 – May 15, 2022

General public provides comments on this public meeting



April – June 2022

FDA develops an implementation plan to move forward with Final Report recommendations



2024 – 2025

FDA engages a third-party contractor to assess progress of its hiring and retention of human drug and biologics review program staff—to meet new PDUFA VII and BsUFA III commitments

Cross-Cutting Recommendations



Enterprise HRIT System



Integrated HR Service Model

Summary Of Conclusions

Summary Of Category-Specific Recommendations

Category	Summary Of Conclusions	Summary Of Category-Specific Recommendations
Strategy	FDA formalized strategic plans and performance goals and gained insight into workforce patterns during the pandemic. Strategies need greater specificity, enterprise-level coordination, and a proactive approach, particularly with retention.	Commit to developing and institutionalizing an enterprise-wide, strategic HR service delivery model, HRIT system, and retention strategies that integrate the entire talent lifecycle.
Culture, Collaboration and Communication	Procedural and operational collaboration has greatly improved. FDA would benefit from a clearly defined Agency-level service delivery model to address customer requirements and integrate efforts of all staff performing HR work.	Engage two-way communication with stakeholders across organizations to cultivate adoption of a standardized service delivery model and engagement strategy that address customer needs and build a culture of trust and respect.
Recruiting and Hiring Process	FDA has advanced its strategic outreach efforts and effectively supported hiring needs through process improvements and multiple hiring authorities. The Agency needs better process coordination, guidance, and integration across HR functions.	Integrate the full talent lifecycle to improve workflow and customer experience; refine HR metrics to sustain improved surge performance; examine the disconnect between qualified candidate referrals versus selections.
Data Management and Systems	FDA has improved hiring process workflows and transparency through its development of ATLAS. FDA does not utilize the full range of available system capabilities to integrate HR processes and data management across the talent lifecycle.	Establish an enterprise HRIT system that leverages integrated data to support process automation and advanced analytics; encourage stakeholder adoption and infuse greater structure in data management and reporting practices.
HR Staff Capability and Capacity	CDER and CBER invest heavily in dedicated HR resources, duplicating efforts of OTS and OHCM. Expanding successful OTS initiatives across the HR workforce could help build consistent, customer-focused capabilities.	Refine workload distribution and management practices; align resources to a customer-focused service delivery model; standardize HR performance goals and accountability; shift to a unified competency model across the HR workforce.

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For more than 100 years, business, government, and military leaders have turned to Booz Allen Hamilton to solve their most complex problems. As a consulting firm with experts in analytics, digital, engineering, and cyber, we help organizations transform.

To learn more, visit [BoozAllen.com](https://www.BoozAllen.com).

FDA RESPONSE TO THE FINAL ASSESSMENT

9:40 AM – 10:00 AM

Melanie Keller

Director

Office of Talent Solutions | Office of Operations

FDA Response



FDA appreciates the results and recommendations found in this final report.

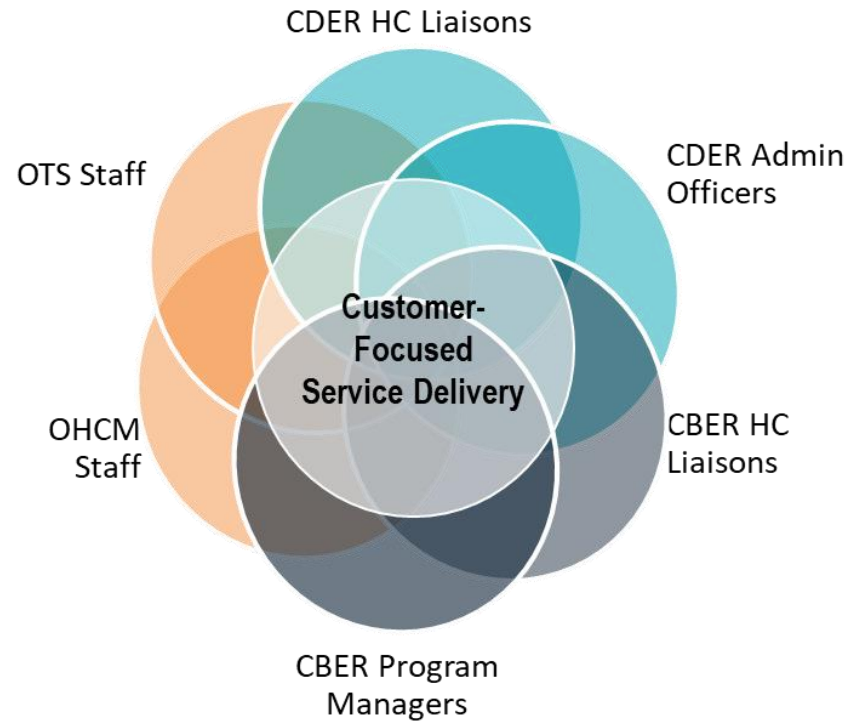


We have made tremendous progress since the first assessment back in November 2017.

- Partnered with our Centers and Offices to establish hiring goals that we met and/or exceeded in FY20 and FY21
- Maintained a relatively low attrition rate
- Deployed the Application Tracking Lifecycle Analysis System (ATLAS) to CBER and CDER for real-time tracking and accountability
- Continued to enhance our focus on Diversity, Equity, Inclusion and Accessibility (DEIA) on current employees and candidates



FDA accomplished this during an unprecedented pandemic that has radically transformed the workforce - the impact of which is still being felt.



Expanding our Focus

Key Recommendations Underway

- Developing a unified Agency-wide strategic human capital plan.
- Designing clear roles and responsibilities for the HR workforce to achieve talent goals.
- Analyzing a digital solution that integrates the entire FDA talent lifecycle.

Q&A / PUBLIC COMMENT

10:00 AM – 10:30 AM

Yashika Rahaman, Ph.D.

Director

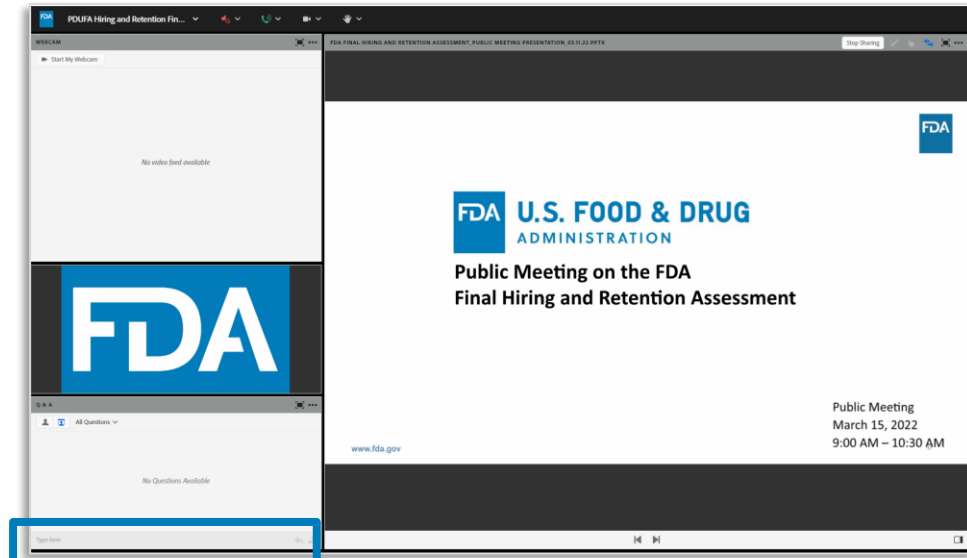
Office of Planning, Evaluation, and Risk Management | Office of Operations

How to Submit Questions or Comments

Adobe chat box during today's public meeting

Please use the format: *Name, Organization: Comment*

NOTE: Questions/comments will be recorded as part of the meeting transcript for public record



Submit your questions

Online via the public docket, anytime through May 15

Go to: <https://www.regulations.gov/document/FDA-2022-N-0083-0001>

Or search: "Hiring and Retention Final Assessment" at www.regulations.gov



Click On "Comment"