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PDUFA VII Cloud

Assessment Summary

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1 Executive Summary

The Prescription Drug User Fee Act (PDUFA) VII agreement specifies the U.S. Food and Drug Administration's (FDA) commitment to "leverage cloud technology to progress regulatory digital transformation" by assessing "challenges or barriers in adoption of cloud-based technologies in applicant-regulator interactions." This report provides a qualitative assessment of the FDA's progress to date in implementing cloud technology within the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER), key challenges to future cloud adoption and opportunities for improvement.

This qualitative assessment is based on data from document reviews, surveys, and interviews to answer the following five (5) research questions:

1. What are the financial, technical, policy, and process-related barriers to - and challenges of - adopting cloud-based technology in applicant-regulator interactions in CDER and CBER?
2. To what extent are these barriers and challenges relevant to the future of cloud-based adoption in the context of applicant-regulator interactions?
3. How do these barriers and challenges change, and what additional challenges and barriers must be considered when expanding interactions across national boundaries, such as regulator-regulator interactions, or sponsor-to-multi-regulator interactions?
4. What future big-picture financial and technical needs may arise during this transition to the cloud environment?
5. What are the benefits to date of adopting cloud-based technology in applicant-regulator interactions?

The FDA has taken significant steps to migrate many of its core business functions to the cloud. It has established access to multiple cloud environments including the Amazon Web Services (AWS) GovCloud and the Microsoft Azure clouds and has made significant progress in addressing the challenge of meeting stringent data security expectations while migrating to cloud-based solutions. Examples of these solutions include systems such as the CDER NextGen Portal (Salesforce Cloud), the CDEROne analytics platform (AWS GovCloud), and the Nexus platform (Appian Cloud) for workflow management, as well as most internal service functions on Microsoft Office 365.

The FDA also faces technical, financial, process and policy challenges that impact its interactions with industry stakeholders and its ability to benefit from cloud solutions. Examples of these challenges include maintaining high performance cloud solutions while meeting federal IT compliance[1] and cybersecurity requirements, streamlining complex hybrid multi-cloud enterprise architecture, re-training existing or hiring new FDA staff to meet knowledge and skill requirements for cloud solutions, and interpreting aged policy language in the context of modern cloud technology.

[1] FDA must adhere to federal standards to identify and categorize data, to include the Federal Information Security Modernization Act (FISMA), Federal Information Processing Standards (FIPS) Publication 199, Standards for Security Categorization of Federal Information, and Information Systems, and National Institute of Standards and Technology (NIST) Special Publication 800-60 Rev. 1 (Volume 1, Volume 2), Guide for Mapping Types of Information and Information Systems to Security Categories.

Methodology

To answer the five (5) research questions, the Cloud Assessment Team used a five (5) step methodology. First, the team documented pain points and benefits from interviews and surveys with FDA stakeholders into a Qualitative Analysis Tool (QAT). Second, the team performed a root cause and effect analysis on each pain point or benefit. Third, the team identified the challenges, barriers, and benefits to date, grouped them into themes, and prioritized the findings. Fourth, the team analyzed and refined the themes into Improvement Opportunities (IO) and Best Practices (BP) categories based on the elements within each. Finally, the team drew conclusions that resulted in challenges and benefits for the FDA's cloud forward movement.

Factor Findings Section reference are listed in the table below for all of the challenges and benefits in this report.

Table 1: Factors Challenges and Benefits

Section Reference	Technical Factor Challenges
3.1.1.1	Legacy System Modernization
3.1.1.2	System Data Security Requirements
3.1.1.3	Federal IT Compliance and Cybersecurity Requirements
3.1.1.4	Data Location Challenges
	Technical Factor Benefits
3.1.3.1	Significant Business Functions Migrated to Cloud
3.1.3.2	System Reliability and Reduction in Downtime
3.1.3.3	Portfolio Consolidation and Inter-Center Access for Cloud Solutions
3.1.3.4	Cloud Infrastructure Scalability
3.1.3.5	More Efficient Development, Deployment, and Updates
	Financial Factor Challenges
3.2.1.1	Costs Associated with Procuring and Maintaining Legacy IT Systems During Cloud Migration
3.2.1.2	Fixed Costs of Adopting Cloud-based Technology
3.2.1.3	Variable Costs of Adopting Cloud-based Technology
	Financial Factor Benefits
3.2.3.1	Cost Savings from CSP Specific Capabilities

3.2.3.2	Cloud Scalability Cost Savings
	Process Factor Challenges
3.3.1.1	Change Management
3.3.1.2	Project Planning
3.3.1.3	Cloud Staffing Capacity and Knowledge
	Process Factor Benefits
3.3.3.1	Agency and Center-Level Services
3.3.3.2	Enterprise Cloud Solutions Break Down Silos
3.3.3.3	Workflow Automation and Business Process Management Through Nexus
3.3.3.4	Increased Industry Collaboration and Workflow Transparency Through Cloud
3.3.3.5	Improved Cloud Governance Processes
	Policy Factor Challenges
3.4.1.1	Records Retention
3.4.1.2	International Submissions
	Policy Factor Benefit
3.4.3.1	Benefits from Adhering to Federal Security Frameworks

Conclusion

The opportunities for FDA to benefit from future cloud adoption are significant. Challenges identified in this assessment must certainly be overcome to fully realize these benefits. But leveraging earlier successes while making strategic investments through careful planning will put the FDA on a more optimal journey to the cloud.

The Cloud Assessment Team would like to acknowledge the contributions of the many stakeholders who provided input for this assessment, including staff from the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Office of Digital Transformation (ODT). In particular, members from the Project Advisory Group (PAG) were instrumental in providing guidance for this study. This assessment would not have been possible without the contributions from these individuals.

2 Introduction and Assessment Overview

2.1 Background

The FDA has made significant progress modernizing its IT architecture to better meet the needs of both internal and external stakeholders. The continued modernization of current IT systems and architecture is necessary to properly fulfill the mission of the FDA. The FDA has taken deliberate actions to adopt cloud-based technologies, with several successful implementations completed and additional migrations ongoing or planned, including:

- Successful deployment of Infrastructure, Platform, and Software-as a-Service (IaaS, PaaS, and SaaS) cloud solutions including Center for Drug Evaluation and Research (CDER) NextGen Portal for non-electronic common technical document (eCTD) submissions and the Nexus Workflow Management and CDEROne Analytics Platforms that streamline workflows and analysis in the drug review process.
- The creation of the Data, Technology, Cybersecurity, and Enterprise Modernization Action Plans (DMAP, TMAP, CMAP, and EMAP) that outline key objectives and action items to achieving a “Cloud-Forward” Information Technology (IT) strategy.
- Ongoing development of a proof-of-concept for the future cloud-based Electronic Submission Gateway (ESG), “ESG NextGen”, meant to further streamline the review process for submissions, which is a PDUFA VII commitment.
- Ongoing migration planning for the transition of legacy on-prem systems such as ESG, Panorama, Document Archiving, Reporting and Regulatory Tracking System (DARRTS) and Mercado to the cloud to achieve economies of scale.

Considering the significant progress the FDA has made to date in adopting cloud-based technologies, this assessment describes the challenges and benefits of pursuing further cloud adoption, specifically CDER and CBER. For the purposes of this assessment, all CDER and CBER cloud technology was assessed, not just the particular technology funded through PDUFA. This is because PDUFA-funded solutions are inexorably linked with other systems and technology throughout the enterprise. This assessment is designed to address the following five (5) key research questions.

1. What are the financial, technical, policy, and process related barriers and challenges of adopting cloud-based technology in applicant-regulator interactions in CDER and the Center for Biologics Evaluation and Research (CBER)?
2. To what extent are these barriers and challenges relevant to the future of cloud-based adoption in the context of applicant-regulator interactions?
3. How do these barriers and challenges change, and what additional challenges and barriers must be considered when expanding interactions across national boundaries, such as regulator-regulator interactions, or sponsor-to-multi-regulator interactions?
4. What future big-picture financial and technical needs may arise during this transition to the cloud environment?
5. What are the benefits to date of adopting cloud-based technology in applicant-regulator interactions?

Research questions 1-5 are addressed in Section 3 of this report.

2.2 Project Overview

Under the PDUFA VII reauthorization agreement, the FDA committed to assess challenges or barriers related to the continued adoption of cloud-based technologies in applicant-regulator interactions. FDA engaged Eagle Hill Consulting (EHC), a third-party contractor, to conduct this assessment. The EHC Cloud Assessment Team set out to address the PDUFA commitment while also focusing on the following goals:

- Assess barriers and challenges in FDA's adoption of cloud-based technologies to support regulatory activities.
- Detail benefits of FDA's intended full-scale adoption of cloud-based technologies.
- Detail potential future financial and technical needs related to cloud-based technologies and migrations.

This qualitative assessment is based on interviews and survey responses from subject matter experts (SMEs) involved in implementing and using cloud-based technologies across the enterprise. The assessment considers input from individuals directly involved in developing cloud-based technologies, as well as those who use the technology services in their day-to-day to conduct the regulatory review process. This balanced input enabled the discovery of both technical and non-technical challenges and benefits of cloud adoption and their impact on the review process. Additionally, the assessment includes input from stakeholders working on backend systems that enable FDA staff to process, store and analyze submission data in the cloud. FDA organizations participating in this assessment include the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Office of Digital Transformation (ODT). The definitions of Challenge, Barrier, and Benefit used in this assessment are:

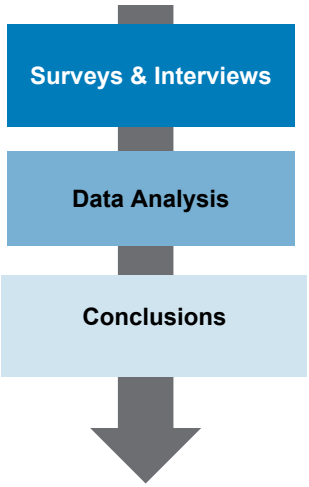
- Challenge: A combination of pain points that hinder or limit the FDA's ability to properly advance its cloud forward mission. These challenges typically can be addressed in the near future, 1-3 years.
- Barrier: Subset of challenges related to the four factors (technical, financial, process, and policy) that are insurmountable in the near future due to a variety of elements currently present within the FDA enterprise.
- Benefit: Advantages observed or realized by the enterprise that are a direct result of the implementation of cloud technology within the organization.

2.3 Methodology Overview

2.3.1 Approach Overview

This report provides a summative assessment of the technical, financial, process, and policy factors related to cloud technology adoption in applicant-regulator interactions. These factors, developed with input from the Project Advisory Group (PAG), were designed to elicit data that provides a comprehensive overview of the challenges, barriers, and benefits to cloud adoption. This assessment includes a review of documents, survey responses, and interview feedback to conduct a qualitative data analysis. This analysis identifies challenges, barriers, and benefits to date, improvement opportunities (IOs), best practices (BPs), and conclusions related to FDA's continued adoption of cloud-based technologies (Figure 1).

Figure 1: Methodology Overview



2.3.2 Document Collection and Review

During this assessment the Cloud Assessment Team performed a review of **51** FDA and industry cloud strategy, architecture, planning, and best practice documents related to cloud technologies. Existing IT and cloud implementation documents were gathered in collaboration with the PAG including IT Annual Reports, IT System and Architecture Diagrams, and other IT architecture, modernization, and strategy documents. These documents were used to inform the Assessment Team's base of knowledge, including the development of the interview and survey questions. These documents also provided a baseline understanding of the current state and an initial source of information that informed stakeholder identification, improvement opportunities and best practice development, and conclusions.

2.3.3 Data Collection Tools

Data collection tools used in this assessment included surveys, interview guides, and interview questions that were co-developed with stakeholders and input from the PAG. The interviews were designed to collect stakeholder insights into the four (4) key factors: financial, technical, policy, and process. The survey was administered in Microsoft Forms and distributed to all interviewed stakeholders. It used Likert scale and open-ended questions tailored to the four factors to gauge respondent perceptions of the challenges, barriers, and benefits surrounding cloud adoption.

2.3.4 Stakeholder Identification

The Cloud Assessment Team worked with the PAG and Office leadership within CDER, CBER, and ODT to identify stakeholders to engage in this assessment. A representative sample of individuals were selected to participate and grouped into three (3) personnel-specific cohorts:

1. **Process Managers** - Center and Office leadership (e.g., directors, assistant directors) and individuals involved in developing application review processes.
2. **End-Users** - Regulatory Project Managers (RPMs) and other staff within CDER and CBER that interact directly with applicants and the systems used during the review process.[2]

[2] *The scope of this assessment did not include direct interaction with users from industry.*

3. **IT Subject Matter Experts** – Individuals who oversee existing FDA IT systems and architecture or have specific knowledge of FDA IT systems, architecture, records retention policies, and cybersecurity.

2.3.5 Stakeholder Interviews and Surveys

The Cloud Assessment Team conducted 74 interviews with 87 stakeholders and received 25 survey responses. Interviews and surveys were tailored to each cohort, allowing stakeholders to speak to their specific experiences and knowledge areas. These interviews and surveys elicited perceived challenges in the FDA's approach or ability to implement cloud-based technologies and the benefits the FDA has gained from its efforts to date. The team distributed targeted surveys to all identified stakeholders and conducted follow-up interviews and surveys as needed to further contextualize and validate documented pain points or benefits.

Figure 2: Qualitative Analysis Approach

2.3.6 Data Analysis

The interviews and surveys yielded 911 qualitative data points related to the implementation challenges, barriers, and benefits of cloud technologies. The team analyzed this data quantitatively to identify pain points; root causes and effects; challenges, and benefits to date; and improvement opportunities and best practices.

The pain points and benefits derived from the interview and survey data revealed commonalities in the challenges and benefits experienced by the stakeholder groups. Likert scales from the survey helped to estimate the strength of these perceptions. These pain points and benefits were tagged and tracked in a Qualitative Analysis Tool (QAT), allowing the team to perform root cause and effect analysis on each pain point or benefit identified.

Root causes pinpoint the primary sources and reasons for an experienced pain point or benefit. Effects help to understand how the pain point or benefit impacts the organization. The team conducted a root cause analysis to identify themes related to common challenges, and benefits related to cloud adoption. The team further refined these themes into Improvement Opportunity (IO) and Best Practice (BP) categories. These themes were organized by the four (4) assessment factors: technical, financial, process, and policy.

2.3.7 Findings

Based on the data analysis, the assessment team developed challenges and benefits by factor. The team grouped the challenges based on related IOs and BPs identified; number of related pain points and benefits; Likert scale analysis; and criticality to cloud technology adoption and achieving regulatory operations goals. The team also consulted with SMEs and considered change management, cybersecurity, and cloud development best practices to refine and further contextualize these findings.

3 Factors and Findings

This assessment is based on a review of qualitative data including interviews, surveys and research to develop the conclusions in this section below. This assessment is based on four (4) key factors - technical, financial, process, and policy – and the topics for each factor under each (Table 2).

Table 2: Topics by Factor

Key Factors	Factor Topics
Technical	• Cybersecurity • Interoperability (integration with existing internal and external systems) • Inter- and intra- organization access • Migration approach/strategy scalability • Connections and configuration • Physical Risk to equipment, servers, and information
Financial	• Fixed costs (setup, access, integration) • Variable costs (internal and external technical support, licensing agreement infrastructure and services operating costs) • Federal acquisition timelines • Legacy IT system maintenance costs of alternatives to cloud environments
Process	• User receptivity to adoption and preparedness • Change management communication and training • Cloud resources/learning materials • Workforce capacity, skills and certifications • User volume • User experience
Policy	• Cybersecurity policy • Records retention • Domestic v. foreign data protection requirements • General Data Protection Regulations (GDPR) • Policy considerations related to movement of data across borders

3.1 Technical

This assessment's analysis included the evaluation of stakeholder responses, which yielded a multitude of pain points related to the technical factor. The technical factor includes challenges and benefits related to software, hardware, infrastructure and architecture design. Topics include:

- Federal IT Compliance and Cybersecurity (Federal requirements such as FISMA, TIC Protocols, Proprietary Data Protection, etc.)
- System interoperability
- Inter- and intra-organizational access
- Migration strategy
- IT architecture
- Legacy system modernization; and,
- Enterprise data management

Technical factors are critical to cloud infrastructure, tools, and applications necessary to facilitate applicant-regulator interactions. This factor encompasses FDA systems which applicants directly interact with, as well as backend systems which provide supporting data management, process and analysis functionality. The FDA faces multiple, complex challenges as it continues to modernize and utilize cloud solutions. It is imperative that new solutions do more than just preserve existing functionality; they should also account for future technical requirements of the FDA, industry, and relevant regulatory bodies such as Congress. This includes enhancements to technology enabling application submissions, systems FDA uses to process submissions, and the data management solutions that allow FDA to meet reporting and auditing requirements.

Any IT modernization effort by the FDA is complicated by the need to maintain legacy integration functionality and the current multi-cloud hybrid environment in which FDA operates. Further, FDA must comply with federal cybersecurity requirements, placing additional complexity on the enterprise infrastructure design. Of important note, the Office of Digital Transformation (ODT), formed in September 2021, has the challenging task of guiding FDA's enterprise IT environment centrally while also growing and maturing its enterprise IT management and cloud capabilities. This effort, while critical, currently faces challenges related to staffing availability, process maturity, and the establishment of enterprise capabilities over historically siloed solution groups.

3.1.1 Technical Challenges

This assessment's analysis included the evaluation of stakeholder responses, which yielded a multitude of pain points related to the technical factor. The pain points are organized into four (4) challenges impacting applicant-regulator interactions. These challenges influence the FDA's ability to design and use technical solutions to support applicant-regulator interactions. This includes methods by which submissions are sent to the FDA, the tools FDA uses to process submissions, and the degree to which FDA can make use of modern cloud capabilities. The prioritized challenges for the technical factor include:

3.1.1.1 Legacy System Modernization

Legacy systems often have many connections and upstream and downstream dependencies which may not translate smoothly to a cloud environment. In the current, multi-cloud hybrid environment, a solution placed into the Amazon Web Services (AWS) GovCloud environment could potentially need to interact with data in the FDA on-prem environment and another system that exists in a different 3rd party cloud environment such as the Azure cloud, Salesforce, or the Appian cloud. Major considerations that add complexity to cloud implementation efforts include:

- Project teams must collect requirements from all upstream and downstream interactions during the planning phase to avoid business activity interruptions. This includes target state requirements from other in-flight or planned systems. Failure to do so leads to scenarios where requirements are not known and business operations are interrupted.

- Federal IT and cybersecurity requirements are necessarily stringent to protect many different types of highly sensitive data. Ensuring compliance with these requirements adds additional coordination challenges and increases implementation timelines.
- Teams must implement a solution without impacting ongoing critical business operations. As noted in other areas of this report, the need to avoid interruption of critical business processes while modernizing systems contributes to higher costs and complexity. This necessitates the operation of legacy, transition, and modernized systems simultaneously. Examples of critical legacy systems that have yet to be successfully replaced with modern cloud solutions include DARRTS, Panorama, and ESG.
- Since the FDA cannot modernize every system at once, modernized solutions such as CDER Next Gen and Nexus must maintain the ability to interact with many forms of legacy technology and data formats. This limitation adds complexity and cost to a solution and increases technical debt for the FDA until the legacy databases are replaced with modern cloud solutions. For example, even if the FDA modernized the submission intake process from an unstructured PDF to a structured data format, any new solution that utilizes legacy submissions would still need to support unstructured PDFs (unless the FDA invested in converting legacy submissions to the new data format).
- Certain new cloud solutions depend on data housed in aged legacy systems, resulting in performance deficiencies. For example, any system that relies on pulling data from DARRTS cannot function if DARRTS is offline or undergoing an update. While modern cloud solutions are online far more consistently and able to update without interrupting user functions, their reliance on a legacy system impedes performance.
- Project teams cannot simply “lift-and-shift” legacy systems when modernizing. Legacy systems likely use aged software that is not compatible with modern cloud solutions. In fact, in some cases performance of the new system might be worse than the legacy on-prem solution. Further, legacy systems were not designed to take advantage of modern capabilities, including automatic scaling, scalable load balancing, cloud-based fail-over, virtual computing, and containerization such as Kubernetes or Docker. This is a common problem for all IT modernization efforts, but its effects should be accounted for.

3.1.1.2 System Data Security Requirements

The FDA continues to experience challenges related to storage, movement, and analysis of data housed in different environments (high, moderate, and low security, cloud and on-prem environments), which prevents cost-savings and operational efficiency.

FDA data is primarily categorized into high, moderate, or low impact levels through a combination of internal risk assessments and federal regulation requirements.

- **Low Impact:** Encompasses data intended for public use, such as press releases. Data loss would not compromise the FDA’s mission, safety, finances, or reputation.
- **Moderate Impact:** Mainly includes data unavailable to the public, such as personally identifiable information like usernames and passwords. A breach of this data can harm the FDA’s operations.
- **High Impact:** Includes sensitive information, such as industry proprietary information and healthcare data. Breaches to FDA systems containing this data would likely be catastrophic—potentially shutting down operations, causing financial impact, and posing a threat to intellectual property.

Key challenges related to system data security include:

- Project teams must design databases for quick data storage and movement based on proper security designations (low, moderate or high) using data segmentation techniques. For example, the FDA houses multiple types of high impact data including market approval, post-market safety, and compliance data. An additional challenge is understanding how to design the system to move data securely and quickly to appropriate connected systems. Both tasks require expertise in data security and cloud environments that the FDA should expand on. While the FDA Office of Information Security has recently released internal guidance on this topic, project teams across Centers lack awareness of this guidance.
- The FDA in many cases must also build custom data intermediaries that can meet federal IT compliance and cybersecurity requirements to facilitate the movement of data between third party cloud service providers and on-prem systems. These intermediaries include instances of MuleSoft that help facilitate data transfers between different third-party cloud environments. This adds architectural complexity and cost to solutions.
- Activities involving data in a hybrid multi-cloud architecture have unique cost factors that need to be evaluated differently than equivalent activities in an on-prem only architecture. This includes the cost of moving data between data centers and the resource cost models used by CSPs (storage, memory and processing). Planning in this environment requires cloud-specific knowledge that is not always recognized or available to project teams, leading to subsequent design, architecture and project execution challenges.
- A hybrid multi-cloud architecture also has a performance impact in terms of the physical distance data must travel between data centers. Distance contributes to latency increases and therefore has a negative impact on business performance.

3.1.1.3 Federal IT Compliance and Cybersecurity Requirements

The FDA complies with a challenging security environment every day. The need to process submissions while remaining in compliance with federal IT compliance and cybersecurity requirements results in a reliance on experience FDA security SMEs. These SMEs have valuable knowledge related to industry proprietary data, personally identifiable information (PII), and sensitive health data, as well as the comingling factors surrounding the hybrid cloud environment.

Federally mandated IT compliance and cybersecurity requirements create additional work for internal FDA security SMEs which can lengthen project duration and result in additional costs and staffing strain.

3.1.1.4 Data Location Challenges

The FDA needs to analyze the feasibility of migrating its existing on-prem databases to a cloud environment. While cloud database solutions have an attractive cost-benefit ratio compared to traditional on-prem data warehouse solutions, there are numerous considerations that are unknown and need to be addressed prior to setting a data migration strategy. These include:

- Regulatory reporting standards requiring the FDA to house certain types of data in perpetuity. At what point does the cost of paying for constant data warehousing in the cloud break even with the cost of owning and operating an on-prem data warehouse?
- The FDA does not currently have clarity on whether it could potentially house submission data in the cloud for a certain number of years, then migrate it to a long-term data storage solution on-prem. This type of scenario could ease the cost burden by keeping relevant, recent submission data in the cloud and aged submission data on-prem where it would not need to be accessed as often. However, this does increase architectural complexity for the enterprise.

3.1.2 Impacts of Technical Challenges

The technical challenges described above lead to six (6) primary effects impacting the FDA's future cloud adoption. These challenge effects were derived through further analysis of individual stakeholder comments. The effects listed below added additional context to the conclusions and findings listed above:

- Challenges and delays in project implementation
- Decreased user adoption or advocacy of cloud solution
- Poor data availability and processing
- Unrealized cloud benefits or cost effectiveness
- Increased project workload
- Increased or unplanned costs

3.1.3 Technical Benefits

Technical benefits include those derived from using IaaS, PaaS, and SaaS solutions in the cloud; increased system scalability; enhanced disaster recovery capabilities; and faster system development, update, and deployment times. Of the benefits gathered for the technical factor, the most impactful ones are:

3.1.3.1 Significant Business Functions Migrated to Cloud

The FDA has successfully migrated several of its critical business functions to the cloud in recent years. This has led to enterprise-level benefits and positioned the FDA to continue maturing its cloud capabilities and internal cloud expertise. Specific benefits include:

- Many Internal service functions were moved to Microsoft Office 365, which has brought most FDA staff administrative functions into the cloud. FDA stakeholders cited many benefits resulting from this move, including the ability to co-edit documents, replacing local file storage on computers with cloud-based storage in OneDrive, and the ability to use multiple devices including personal cellphones for email office applications. These technical benefits contribute to increases in workplace efficiency and satisfaction.
- Several Infrastructure-as-a-Service (IaaS) and Platform-as-a-Service (PaaS) solutions have been implemented for critical business functions including MuleSoft Cloud (message brokering), the CDEROne platform (dashboards, analytics, comprehensive search, business insights, and reporting), and Nexus (business process management).
- These platforms have also had a positive impact on user's ability to access, use, design, develop and deploy applications residing on them. Users reported that the process of requesting permission to develop applications and the act of developing applications is easier on platforms like Nexus and CDEROne than it is on-prem.
- Stakeholder comments mentioned an improved submission process between applicant and regulators through the CDER NextGen Portal. The CDER NextGen Portal has had a significant impact on applicant-regulator interactions since its deployment. Handling all non-standard industry submissions, the NextGen Portal exemplifies the kind of impact cloud solutions can have on applicant-regulator interactions. The CDER NextGen Portal also serves as an entry point for many different types of cloud technologies, including exposing FDA systems to outside users, utilizing AWS GovCloud, utilizing Okta for identity and access management, and establishing a connection for the movement of data between the cloud and on-prem systems. Because non-standard submissions required

significant manual effort to process, they were a prime candidate for a portal where applicants enter data into fields as part of their submission, rather than having FDA staff process the data after submission. Additional impacts CDER NextGen Portal has had on the FDA and industry partners include:

- Increased process visibility and communication capabilities between FDA reviewers and industry stakeholders.
- Minimized reliance on paper, media, and email submissions from applicants.
- Automatic workflow generation through integration with CDER Nexus.

Challenge Note: The FDA is continuing to consolidate components of these business functions under these platforms, streamlining the portfolio of applications and the overall architecture of the FDA's IT environment.

3.1.3.2 System Reliability and Reduction in Downtime

Cloud resource architecture involving virtual servers reduce system downtime and ensure a reliable infrastructure for business to continue. CSPs also provide failover capabilities and rapid response times to outages, in addition to automatic backups for more efficient disaster recovery.

3.1.3.3 Portfolio Consolidation and Inter-Center Access for Cloud Solutions

As the FDA's technical environment continues to mature, its ability to develop solutions in the cloud that can be leveraged by multiple Centers, Offices, and Divisions across the enterprise increases. Over time this means that the FDA can consolidate its portfolio of applications on cloud-based platforms, reducing business capability duplication across Centers and offices. The impact of this benefit spans the technical, financial and process factors, since it results in reduced architectural complexity, cost-savings through portfolio rationalization, and process efficiency increases.

3.1.3.4 Cloud Infrastructure Scalability

Increased cloud infrastructure scalability allows FDA to obtain additional resources more easily (e.g., virtual servers/machines, EC2 instances, etc.) without the need for additional capital projects to expand capacity. Cloud Service Providers (CSPs) allow for allocating more resources during busy submission times to avoid disruption of service as well as increased efficiency in the review process leading to reduced overhead costs.

3.1.3.5 More Efficient Development, Deployment, and Updates

Cloud environments allow project teams to benefit from scalable development, test and production environments and reduced deployment time throughout the software development lifecycle. Many cloud environments allow project teams to establish access to a sandbox environment where they can experiment with new products and features in a safe and scalable way which does not impact business operations. Updates are also far faster in a cloud environment compared to the update process for on-prem systems since new instances can be brought into Prod without taking the operational instances offline first.

3.1.4 Impacts of Technical Benefits

The technical benefits described above lead to seven (7) primary effects impacting the FDA's future cloud adoption. These benefit effects were derived through further analysis of individual stakeholder comments. The effects listed below added additional context to the conclusions and findings listed above:

- Enhanced Cloud Development Lifecycle
- Reduced Costs
- Increased Review Process Efficiency
- Improved User Experience
- Consistent Modernization of System Feature and Capabilities
- Improved Database Capability
- Reduced System Downtime or Risk of Data Loss

3.2 Financial

This assessment's analysis included the evaluation of stakeholder responses, which yielded a multitude of pain points related to the financial factor. The financial factor encompasses challenges, and benefits related to the costs of adopting cloud technology at the FDA, including topics such as:

- Fixed costs
- Variable Costs
- Costs associated with Legacy IT Systems
- Administrative Procedures

Financial considerations are critical in providing accurate budget forecasting for cloud related projects. This includes financial considerations in the FDA's cloud forward movement; fixed and variable costs of adopting cloud-based technology; as well as costs associated with maintaining legacy systems and administrative procedures.

Challenges arise from the differences in IT pricing from traditional on-prem to cloud-based solutions. As the findings of this report will emphasize, understanding the differences in financial planning for cloud solutions is key to modernization efforts at FDA. Financial planning decisions will dictate if a cloud solution is the optimal and most cost-effective option. The FDA may have some difficulty accurately planning the overall cost of a solution as it will need to plan for future spikes in demand, storage capacity, projected service utilization, and data volumes moving between data centers during its operation. Alternatively, if utilized correctly, the FDA could potentially save on costs as CSPs can be scaled to the FDA's needs and servers can be spun up or down as needed to optimize hardware utilization.

3.2.1 Financial Challenges

Financial considerations are key to an efficient and cost-effective transition to the cloud. These include anticipating unplanned costs, preventing inefficient spending, and properly planning for legacy IT system replacement and workforce transition to the cloud. The prioritized challenges for the financial factor include:

3.2.1.1 Cost Associated with Procuring and Maintaining Legacy IT Systems During Cloud Migration

The costs associated with procuring and maintaining legacy systems during new cloud system development poses a significant challenge to the enterprise. The current hybrid environment at the FDA contributes to the financial challenges the enterprise faces when continuing to migrate to the cloud. Maintaining existing legacy systems is costly due to hardware and software maintenance, security patching, downtime, and integration challenges contributing to productivity

loss. This continued spending on legacy system maintenance, hinders the ability to use funds on new cloud solutions. The following challenges are specific to legacy system procurement and cloud modernization at the FDA:

- There were inefficiencies observed with the current procurement process for legacy systems. Specifically, legacy system resource management including resource planning and estimation were examples where stakeholders mentioned wasteful spending. Since on-prem systems cannot be scaled up or down, provisioning for these systems often leads to over-ordering and under-utilization, therefore this overprovisioned hardware is often sitting around not being used.
- The need to support legacy IT systems for business continuity during the development and transition to the cloud increases the overall cost of migration. The costs to move data across cloud and on-prem environments is higher because both environments are used in the review process. In addition, the resource and personnel costs to maintain both environments are higher during this transition.
- Legacy system maintenance costs are high due to the need for lengthy upgrades and updates. Stakeholders noted on-prem upgrades can take up to a year to complete. By that time, solutions are outdated and require patching again. As long as legacy systems such as DARRTS must be maintained, the FDA will not be able to take full advantage of cost savings from cloud adoption.

3.2.1.2 Fixed Costs of Adopting Cloud-Based Technology

The FDA's continued efforts to adopt cloud solutions are tied to certain fixed costs that remain relatively constant regardless of the level of cloud usage or size of the cloud infrastructure. The following financial challenges are related to these fixed costs.

- The implementation of cloud solutions that are replacing legacy systems come with a period of a fixed costs in order to maintain business continuity. This is due to the inability of legacy software components to be supported in the cloud environment, which prevents the FDA from simply recreating ("lift and shift") a legacy solution in the cloud. While the new solution is being built and deployed, the legacy solution must be kept operational for as long as it takes to migrate all its business capabilities into the new cloud solution. This is called the transition period and it requires the FDA to pay to keep both the legacy and the target state solution operational during this time. This problem is not unique to the FDA, but it has significant impacts on budgeting at the FDA that should be noted.
- The FDA's multi-cloud environment increases costs through the need to build custom cloud-to-cloud communication intermediaries that meet required federal IT compliance and cybersecurity policies. These policies can sometimes prevent CSPs from utilizing their own data broker solutions, requiring additional spending for application teams for custom built solutions.
- When considering FISMA High environments, strict security requirements result in a restricted pool of vendors who can provide FISMA High approved COTS solutions. This smaller pool of vendors means higher costs for products and services as the FDA has less negotiation power during the selection phase. It also limits overall technical innovation due to lower variety in solution selection. This sometimes includes learning periods needing to be built into contracts while vendors get up to speed on security requirements.

3.2.1.3 Variable Costs of Adopting Cloud-Based Technology

The FDA's continued efforts to adopt cloud solutions are tied to certain variable costs that fluctuate based on the level of cloud usage and the amount of cloud resources consumed. The following financial challenges are related to these variable costs.

- There is a general lack of knowledge and guidance available to teams for estimating variable costs when utilizing third-party CSPs for cloud solutions. Poor planning for cloud service charges and lack of expertise in contract cost structures can cause costs to exceed planned estimates. These unplanned costs typically result from higher than anticipated resource usage, sub-optimal services selection, and transfers of data between both cloud-to-cloud and cloud-to-on-prem. Some application teams noted that there is insufficient guidance on usage-based cost structure, as well as cloud service-based cost differences that vary from team to team. This lack of expertise often leads to sub-optimal cost models that are not always cost-beneficial. Additional stakeholder experiences pointed to a lack of understanding of the differences between on-prem resource spending and cloud cost models.
- The FDA's current hybrid, multi-cloud environment increases variable data transfer costs as additional CSP fees are incurred when moving information across disparate environments. The need to use a Trusted Internet Connection (TIC) in the FDAs hybrid-cloud and multi-cloud environment causes higher costs for data movement as data must be routed to the HHS TIC before moving between 3rd party cloud environments or the FDA on-prem environment. There is a cost associated with moving data from the west coast to the east coast. Given the amount of data being transferred and the number of Application Programming Interface (API) calls the FDA makes daily, the costs can add up quickly. This is due to CSP cost models which charge per API call.
- Assessing future costs of cloud projects remains difficult due to evolving data storage and usage volume, including assessing the costs to move records to the cloud and predicting the costs of growing submission file sizes from industry.
- There is a lack of established methods and best practices for assessing the tangible and intangible costs and benefits of cloud projects. This includes estimating future maintenance and usage costs and the quantification of intangible or secondary benefits offered by cloud such as disaster recovery and security. The lack of established guidelines governing how cloud projects should document these costs makes determining the overall cost effectiveness of cloud efforts difficult. This includes assessing the costs to move records data to the cloud specifically from the Electronic Documents Room (EDR) system, as well as growing submission sizes and their impact on data processing costs.

3.2.2 Impacts of Financial Challenges

The financial challenges described above lead to seven (7) primary effects impacting the FDA's future cloud adoption. These pain point effects were derived through further analysis of individual stakeholder comments. The effects listed below added additional context to the conclusions and findings listed above:

- Increased or Unplanned Costs
- Challenges or Delays in Project Implementation
- Decreased User Adoption or Advocacy of Cloud Solutions
- Unrealized Cloud Benefits or Cost Effectiveness

- Insufficient Funding
- Increased Project Workload
- Poor Data Availability and Processing

3.2.3 Financial Benefits

Financial benefits focused on reduced costs from unique CSP capabilities and offerings and cloud scalability. Financial benefits also include an enhanced cloud development lifecycle, pointing to efficiencies in development of technology presented by the cloud. Of the benefits gathered for the financial factor, the most impactful are:

3.2.3.1 Cost Savings from CSP Specific Capabilities

CSP-specific capabilities offer financial benefits previously unattainable with legacy IT systems. These include costs savings through reduced operational costs, staffing, and system downtime productivity loss. While these cost impacts are not unique to the FDA, they still have a substantial effect on applicant-regulator interactions and PDUFA funding.

- CSP-managed services provide regular maintenance, upgrades, and updates to applications without additional investments, as opposed to fixed and operating costs tied to on-prem maintenance of legacy systems. Infrastructure and overhead cost savings stem from CSP contracts including these services that previously fell on internal infrastructure teams. Cost savings increase as aging legacy system infrastructure is decommissioned and replaced with rebuilt cloud solutions.
- CSPs have built in redundancies and failover reducing system downtime, improving business continuity, and reducing costs during downtime.
- Reduction in IT staffing is another financial benefit due to CSP managed services that handle maintenance duties. Particularly, disparate center, office and division teams can reduce or eliminate their infrastructure or cloud development teams as IaaS and PaaS models replace their functions in a service model. Not only is this a direct cost savings; it also allows the FDA to consolidate infrastructure and cloud teams within ODT, its enterprise office. This simplified enterprise staffing model consolidates the infrastructure and cloud body of knowledge and cloud service business functions within ODT. Overall, this increases efficiency which means FDA funding for applicant-regulator interactions goes further.
- Teams within CDER reported to have benefitted from lower costs compared to on-prem through utilizing AWS GovCloud savings plans. These teams also benefited from cloud capabilities such as dynamic resource planning and scalability. Cloud scalability in particular is a powerful benefit to teams, as they can spin up and spin down hardware as needed based on real time or near real time demand. This benefit is discussed in more detail in the Cloud Scalability and Cost Savings benefit section.

3.2.3.2 Cloud Scalability and Cost Savings

Scalability in cloud solutions offers cost-efficiency through the “on-demand” model where the FDA only pays for the resources used, preventing overprovisioning that can occur in traditional on-prem systems.

- Dynamic resource planning for cloud solutions means applications can be scaled up and down in response to real time demand. This allows project teams to keep their resource utilization rates consistently high. In traditional on-prem solutions, even with virtual machines, it is much more difficult for the FDA to keep utilization consistently high. Instead,

project teams often need to plan for peaks in demand, resulting in utilization rates being relatively low outside of these peak demand times. Additionally, when project teams no longer need certain resources, they can switch them off in the cloud, whereas in an on-prem data center, the FDA would still be in possession of any unused hardware, resulting in cost inefficiencies.

- The ability to develop solutions in the cloud that can be leveraged by multiple Centers, Offices, and Divisions across the enterprise, decreasing spending on siloed solutions with similar purposes.
- Cloud solutions enable the FDA to obtain additional resources for projects (e.g., virtual servers/machines, EC2 instances, etc.) on demand without the need for additional capital projects to expand capacity. It is much easier and faster to provision infrastructure for project teams in the cloud than it is on-prem, where hardware must be bought and installed.

3.2.4 Impacts of Financial Benefits

The Financial benefits described above lead to six (6) primary effects impacting the FDA's future cloud adoption. These benefit effects were derived through further analysis of individual stakeholder comments. The effects listed below added additional context to the conclusions and findings listed above:

- Reduced Costs
- Enhanced Cloud Development Life Cycle
- Reduced System Downtime or Risk of Data Loss
- Improved User Experience
- Consistent Modernization of System Features and Capabilities

3.3 Process

This assessment's analysis included the evaluation of stakeholder responses, which yielded a multitude of pain points related to the process factor. The process factor of this assessment focuses on key aspects of change management during cloud adoption. These include understanding and improving user experience and receptivity, developing effective communication and training materials, and providing sufficient cloud support staffing capacity and subject matter expertise. Topics for this factor include:

- User receptivity to adoption and preparedness
- Change management (communication, training)
- Cloud staffing and subject matter expertise

Process challenges impact the FDA's success in applicant-regulator interactions. Particularly, change management effectiveness dictates how quickly and efficiently the FDA can get users to use a new system or feature. From an enterprise portfolio management perspective, utilization of systems and features is key to justifying their cost. While there is always a period of learning and trial-and-error with any new system rollout, the quality of training and communication has a significant impact on how long that period will be. Additionally, the FDA's ability to gather and make use of cloud-specific expertise throughout the enterprise also dictates the quality of technical solutions and the efficient use of funding.

3.3.1 Process Challenges

Process considerations are essential to a seamless and comprehensive Cloud Development Lifecycle (CDLC). Focusing efforts to improve cloud-based development procedures at the FDA can improve overall quality of post-production solutions, end user experiences, and adoption.

Grouped together, the pain points are organized into three (3) challenges impacting applicant-regulator interactions: change management, project planning, and cloud staffing capacity and knowledge. While some of the identified challenges are common to all IT projects, cloud or otherwise, they nonetheless affect the ability of the FDA to design, develop and utilize cloud solutions in applicant-regulator interactions. The challenges noted here result in operational inefficiencies that slow submission processing and therefore increase the time-to-market for industry partners. It also places additional strain on FDA resources, including personnel, which has an impact on how efficiently the FDA can utilize PDUFA funding in pursuit of agreed upon goals. The top challenges for the process factor include:

3.3.1.1 Change Management

Change management challenges include a need for increased or improved user engagement and communication to drive and support change to cloud systems during and after the introduction of cloud resources. FDA users and process owners reported that there was insufficient communication regarding how new cloud technologies would impact their daily work. For applicant-regulator interactions this means that the FDA could more optimally implement its solutions and prepare its staff to make use of the latest cloud technology. As a result, the impact that cloud solutions have on improving the submission intake process is slowed.

Change management is a significant challenge for any organization of sufficient size and complexity, and the FDA is no exception. The FDA makes great strides in streamlining its implementation of process and technology changes and must continuously assess and address change management challenges. Specific change management challenges gathered as part of this report include:

- Challenges related to early communication regarding data and records retention capabilities, reliability of cloud systems, and how they meet federal requirements. When users were not engaged well enough regarding new system or feature rollouts, they reported having lower rates of adoption and trust in new cloud solutions. This increases barriers to change for the enterprise.
- Challenges related to communication regarding how cloud technologies would affect the review process and ways of working. Users noted that while communications to announce new systems and the retirement of legacy systems was effective in building awareness of the change, follow-up communications were insufficient in building the desire, knowledge, ability, and reinforcement to make changes stick. Additionally, difficulties with communication of cloud transition purpose, timelines, and expected process negatively impacts user experience and adoption and increases the likelihood that they will go back to using legacy systems.
- In some cases, training materials can be tailored more specifically to specific functions, skill-levels, and familiarity of users. The review process itself can also increase barriers to change and user adoption. Specifically, when there is a lack of a multi-format training approach that suits the user's work this can ultimately disengage them from adopting new cloud solutions. Sometimes this leads to users defaulting to using legacy processes or systems, ultimately hindering faster cloud adoption.

- Users reported that at times new systems did not perform all the functions of the legacy system at initial deployment. They instead had to use the new and legacy systems simultaneously until all legacy capabilities were live in the new system. Those users described situations where they instead chose to just use the legacy system, which results in lack of adoption of new cloud technology and lower overall utilization of new solutions.
    - Regarding ODT's function to manage the enterprise portfolio of products and applications, FDA stakeholders indicated that some enterprise solutions were imposed upon them but did not meet all business capabilities and user requirements that the legacy system provided. Specifically, teams reported a lack of opportunities for cross-center and cross-office collaboration on new features and necessary new system requirements. This resulted in project teams needing to either modify their solutions to accommodate the new product's capabilities or engage with ODT after the fact. In both cases there was an impact to their work.

3.3.1.2 Project Planning

Project Planning plays an important role in the cloud forward approach by ensuring the appropriate stakeholders understand the requirements of the cloud solution. This includes engaging users early in the design process to understand what functionalities need to be implemented to avoid unnecessary updates after rollout.

User engagement to understand needs and system requirements often occurs too late in the development process, requiring multiple revisions and negatively impacting change management and adoption efforts. More upfront gathering of stakeholder requirements and earlier and more frequent user engagement will result in higher quality rollouts and new system adoption.

3.3.1.3 Cloud Staffing Capacity and Knowledge

Providing sufficient staffing capacity and skillsets to facilitate the journey to the cloud is critical to successful cloud adoption. Cloud technology and integration requires specialized knowledge of both FDA's unique IT architecture and cloud best practices. The current staffing capacity and knowledge base is not sufficient to support an optimal path to cloud.

- Lack of cloud subject matter expertise during the acquisitions process prevents teams from making informed decisions between cloud solutions and providers and whether on-prem or cloud solutions are more appropriate or cost-effective.
- Enterprise architecture planning and implementation subject matter expertise is underdeveloped among staff with legacy IT-specific knowledge. This negatively impacts the ability to develop strategies and solutions that connect or migrate on-prem legacy systems to the cloud.

3.3.2 Impacts of Process Challenges

The process challenges described above lead to four (4) primary effects impacting the FDA's future cloud adoption. These pain point effects were derived through further analysis of individual stakeholder comments. The effects listed below added additional context to the conclusions and findings listed above:

- Decreased User Adoption or Advocacy of Cloud Solutions
- Challenges and Delays in Project Implementation
- Unrealized Cloud Benefits or Cost Effectiveness
- Poor User Experience

3.3.3 Process Benefits

Process benefits are derived from recent enterprise service and process consolidation under ODT; the reduction in silos due to cloud technology; enhanced workflow automation; better industry collaboration and workflow transparency; and good cloud governance. The top effects measured for the process factor benefits are Improved User Experience, Enhanced Cloud Development Lifecycle, Reduced Costs, Increased Review Process Efficiency, and Reduced System Downtime or Risk of Data Loss. Of the benefits gathered for the process factor, the most impactful ones are:

3.3.3.1 Agency and Center-Level Services

There are both agency-level and center-level services that aid in the procurement, solutioning and implementation of cloud and IT solutions at the FDA. For agency-wide efforts, ODT was established with the goal of providing vision and leadership in IT, data and cybersecurity for the FDA's enterprise IT practice. As part of its mission ODT consolidates certain business functions, including managing the enterprise portfolio of products and services and also providing certain services to the enterprise, including cloud consulting and infrastructure provisioning. Some FDA stakeholders reported that working with ODT was of great benefit. In terms of applicant-regulator interactions, ODT directly supports PDUFA related functions and IT components by contributing to enterprise level efficiency gains in operations, services, and business capabilities and providing cloud subject matter expertise. Specific benefits include:

- CDER received consultations from ODT that allowed them to do a side-by-side comparison of test environments for a proposed solution comparing on-prem and AWS GovCloud resulting in AWS performing comparably to the on-prem solution. This allowed the CDER team to make an educated decision about which solution best met their requirements. ODT also provided insight which allowed the CDER team to better understand the costs of operating in the cloud.
- ODT provides cloud consultation services to FDA project teams both by request and as part of the IT Intake Process. This means individual offices and divisions do not have to keep cloud SMEs on staff; instead, they can go to ODT to receive it. This streamlines the FDA organizationally and centralizes the FDA's knowledgebase.
- ODT is gradually establishing enterprise product approvals, which for the FDA means that centers are not creating their own tech stacks in silos. Over time this effort will reduce duplication of business capabilities and applications and will contribute to an overall increase in operational efficiency for the enterprise.

In addition to ODT services, other center-level services exist to help with the FDA's current IT needs and its cloud-forward approach. The CDER Informatics Program Management Office (PMO) serves as the central point for coordination, collaboration, and escalation of business informatics activities among projects, CDER offices, and the BIG Board. CDER PMO made budgeting easier by implementing the IT Intake Process form. CDER PMO works strategically to turn business needs and pain points into potential solutions, while also providing cost estimations and recommendations. Additionally, the office offers software licensing information and insight into existing IT projects and CDER software/hardware architecture. The CDER Business Informatics Governance (BIG) Board works with CDER PMO and helps coordinate the enterprise cloud strategy by managing vendors and system integrators, in addition to choosing software. The BIG Board also engages with ODT for deployments and approvals.

3.3.3.2 Enterprise Cloud Solutions Break Down Silos

Compared to on-prem solutions, cloud technology combined with enterprise-level architecture planning makes it easier for FDA teams to provide access to users between centers, offices and divisions. Effectively this means that information silos and operational silos can be more easily broken down as teams understand that it is easier to collaborate in cloud environments. For example, even though CDEROne is a platform intended to service CDER offices, when CBER wanted to develop and host an application on the platform it was possible due to the PaaS model CDEROne is built upon. If an application team wishes to provide access to a user in a different center or office, the proper identity and access management permissions are all that needs to be set up. There is no need to install any applications on desktop or laptop devices. For applicant-regulator interactions, this means that industry partners can be confident that the FDA's modern cloud solutions facilitate faster submission processing and increased cost efficiency for solutions.

3.3.3.3 Workflow Automation and Business Process Management Through Nexus

The CDER Nexus solution, hosted in the Appian cloud, has had a profound effect on the way that CDER manages its business processes. For the purposes of applicant-regulator interactions this is a critical component of the FDA's cloud strategy which will facilitate the shifting of business processes into the cloud and allow the FDA to design modern workflow automation techniques, including for the processing of industry submissions. Over time CDER plans to migrate all its internal business process management into Nexus and off legacy on-prem solutions - DARRTS and Panorama. Benefits include:

- Workflow automation is built into the processes of other systems such as CDER NextGen Portal. The NextGen Portal automatically generates a workflow in Nexus when a submission is received. This increases the pace at which the FDA can process a submission, reduces manual workload for FDA staff, and enables the FDA to consistently integrate workflows into other functions such as workflow process status tracking and data management.
- Nexus is a cloud platform which allows users to access, design and deploy applications more easily compared to the legacy on-prem solutions. Solutions are therefore cheaper and faster to set up for teams within CDER.

Benefit Note: There are other examples of business process improvement through cloud solutions including external portal services (CDER NextGen Portal), Analytics (CDEROne Analytics), and cloud infrastructure environment support as a service (CDEROne Platform).

3.3.3.4 Increased Industry Collaboration and Workflow Transparency Through Cloud

For the CDER NextGen Portal and its related systems like Nexus FDA stakeholders reported far greater levels of transparency and communication in the new cloud systems compared to the legacy on-prem solutions. As a result of standing up cloud environments, the FDA is now able to interact directly with industry stakeholders as part of the submission process. Previously, limitations related to on-prem solutions meant that the industry and FDA staff could only communicate via email. Interacting via the NextGen Portal has reportedly been hugely successful because email communication had several serious drawbacks including difficulty with email record keeping for reporting purposes; difficulty with keeping track of email conversations; and

issues related to staff turnover and not knowing who to email when an issue came up. Workflow transparency has also cut back on the number of communications needed since industry and FDA staff can get updates on the status of specific steps in the process via the portal.

These improvements for both the FDA and the industry improve applicant-regulator interactions in terms of user experiences, as well as process efficiency and workflow transparency.

3.3.3.5 Improved Cloud Governance Processes

CDER implemented several improvements to its governance ecosystem that have positive effects on its ability to utilize cloud technology to better serve applicant-regulator interactions. In addition to best practices involving architecture and technology portfolio governance, CDER also has created a Project Management Office (PMO). The CDER PMO helps process CDER IT Intake requests and helps keep the CDER portfolio of products and solutions as streamlined as possible. Stakeholder feedback within FDA indicates that the PMO has been very successful and well received, especially because it features the following support components:

- Inclusion of end users within Integrated Project Teams (IPTs) increases adoption of the cloud by providing opportunities for early and regular feedback on system performance and capabilities from users.

The use of IT Liaisons to collect feedback and requirements from multiple user groups across the FDA helps build the case for change to enterprise cloud solutions.

3.3.4 Impacts of Process Benefits

The process benefits described above lead to seven (7) primary effects impacting the FDA's future cloud adoption. These benefit effects were derived through further analysis of individual stakeholder comments. The effects listed below added additional context to the conclusions and findings listed above:

- Improved User Experience
- Enhanced Cloud Development Life Cycle
- Reduced Costs
- Increased Review Process Efficiency
- Improved System and User Communication
- Reduced System Downtime or Risk of Data Loss
- Consistent Modernization of System Features and Capabilities

3.4 Policy

One of the goals of this assessment was to determine whether the FDA was facing any current policy related challenges or barriers. While this subject area yielded fewer responses overall, several areas of interest were still uncovered. The policy factor of analysis focuses on federal cybersecurity, records retention, and data protection policies that impact cloud adoption. Policies are often federally mandated and often include language that has not been updated in many years. Topics for this factor include:

- Federal IT Compliance and Cybersecurity (Policy Language, Security Frameworks, etc.)
- Records retention
- Federal data protection requirements

- International submissions

Some respondents indicated that outdated policy language begged certain questions related to the FDA's ability to fully utilize cloud technology. For example, some stakeholders believed that an assessment of existing policy language would be prudent to ensure that there would be no issues with future permanent migrations of data into 3rd party cloud environments. However, in consultation with FDA SMEs it was determined that policy language was not having a material effect on the FDA's cloud strategy at the moment. Therefore, our analysis features challenges related to records retention and international submissions which are more concrete examples of policy related challenges and barriers.

3.4.1 Policy Challenges

This assessment's analysis included the evaluation of stakeholder responses, which yielded a multitude of pain points related to the policy factor. Grouped together by logical relationships, the pain points are organized into five (5) challenges impacting applicant-regulator interactions. Though there are comparatively fewer total policy pain points, challenges within this factor have a large effect on the ability to adopt cloud solutions. These include how security policies negatively impact the ability to move data seamlessly between cloud and on-prem environments, how existing records retention policies will be addressed in the cloud, how differences in records and data management will be resolved across borders, and how security of information in the cloud will be maintained. The top challenges for the policy factor include:

3.4.1.1 Records Retention

Strategies for managing and retaining records in the cloud to maintain compliance with Part 11 (21 CFR 11) remain ongoing, requiring additional work from IT project teams to develop individual plans. This includes compliance with public docket measures (21 CFR 11.2(b)(2)); how cloud systems used for submissions will "ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records" (21 CFR 11.10) and other aspects of Part 11 compliance.

3.4.1.2 International Submissions

The topic of international submissions yields challenges and barriers which extend beyond what the FDA is able to control on its own. For instance, it is acknowledged that sponsors face challenges when submitting their applications to multiple regulatory agencies across borders. This is because the submissions must be tailored for each individual regulatory body including such factors as data format and standards, file size, submission format, language, and local law. The FDA understands that for applicants it would be more cost efficient and faster to submit one application to all regulatory bodies, but that would require the cooperation of multiple regulatory bodies as well as agreement among the applicant community.

For this reason, the topic of unified submission criteria across international borders is considered a challenge for the FDA. For its part the FDA continues its communication with the applicant community to facilitate discussions on how to enhance the submission process for all parties.

3.4.2 Impacts of Policy Challenges

The policy challenges described above lead to three (3) primary effects impacting the FDA's future cloud adoption. These pain point effects were derived through further analysis of individual stakeholder comments. The effects listed below added additional context to the conclusions and findings listed above:

- Unrealized Benefits or Cost Effectiveness
- Increased Costs
- Increased Project Workload

3.4.3 Policy Benefits

Policy benefits at the FDA are a result from the robust policy measures taken by the enterprise as mentioned in this section. The continued investment in security solutions, and abidance to federal guidance and frameworks has resulted in compliant and secure IT systems. This assessment gathered only a few datapoints for policy benefits through our interviews. The way that the policy factor is framed makes this a predictable result, considering the FDA is aiming to comply with policy language and policy language is designed to constrain agency activities.

3.4.3.1 Benefits of Adhering to Federal Security Frameworks

The FDA's efforts to adopt and implement current federal security frameworks like Zero Trust and TIC 3.0 elevate the security standards for all newly implemented cloud solutions. ODT's FDA Zero Trust Cybersecurity Network Defense Implementation Plan serves as a roadmap for gradual implementation. The adoption of Zero Trust at the FDA is expected to alleviate security related cloud adoption difficulties including enhancing user experience, improved security visibility, categorized and inventoried data, and cloud and application integration. Clear Federal regulations also enable technology companies to innovate with confidence, knowing that the Federal clients may have high interest in their new solutions.

3.4.4 Impacts of Policy Benefits

The policy benefits described above lead to one (1) primary effect impacting the FDA's future cloud adoption. This benefit effect was derived through further analysis of individual stakeholder comments. The effect listed below added additional context to the conclusions and findings listed above:

- Enhanced Cloud Development Lifecycle

Appendix

This section provides additional context to terms and topics included throughout the document, as well as additional survey data that aided the construction of this report.

A. Glossary of Common Terminology and Acronyms

Term or Acronym	Definition or Explanation
API	Application Programing Interface
ATO	Authority To Operate
AWS	Amazon Web Services
Best Practice	A method, technique, process, or approach that is widely recognized as the most effective and efficient way to achieve a goal or desired outcome. Best practices are established through experience, research, and continuous improvement efforts in a particular field or industry.
CBER	FDA's Center for Biological Evaluation and Research (CBER) regulates biological products, including blood and blood products, blood derivatives, vaccines, allergenics, gene therapies, cellular therapies, and xenotransplantation, certain drug products, HIV test kits, medical devices involving blood and human cells and tissue products.
CDER	FDA's Center for Drug Evaluation and Research; performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the U.S. Food and Drug Administration (FDA), CDER regulates over the counter and prescription drugs, including biological therapeutics and generic drugs.
Cloud/Cloud Computing	The practice of using a network of remote servers hosted on the internet to store, manage, and process data, rather than a local server or a personal computer
CDLC	Cloud Development Lifecycle (CDLC) refers to the set of processes, methodologies, and best practices involved in developing and deploying applications or services in the cloud computing environment. It is a specialized version of the traditional software development lifecycle (SDLC), adapted to address the unique characteristics and challenges of cloud-based development.
COTS	Commercial Off The Shelf (COTS) refers to products or solutions that are available to multiple customers. They are intended to be used as-is without significant alterations to meet specific requirements.

Term or Acronym	Definition or Explanation
CSP	Cloud Service Provider (CSP) is a third-party company that offers a range of cloud computing services and resources to the FDA. CSPs manage the infrastructure, servers, and software necessary to deliver these services.
Database	An organized collection of structured data that is stored electronically in a computer system.
DSC	Digital Services Center (DSC) is an internal FDA organization that serves as a shared services provider for the FDA's centers and offices. The organization supports the FDA through rapid Agile development, governance, and secure operational environments.
eCTD	Electronic Common Technical Document.
EDR	Electronic Document Room (EDR)
End-Users	One of the three (3) major Cohort groups in this assessment. Individuals within the FDA who use IT to fulfill their job functions. This includes teams using ODT and OBI services, teams using platforms to develop applications, and individuals using a specific application, to name a few.
ETA	Estimated Time of Arrival
FDA	Food & Drug Administration
FedRAMP®	Federal Risk Authorization Management Platform (FedRAMP) provides a standardized approach to security authorizations for Cloud Service Offerings
FiDLE	FDA Intelligent Data Lifecycle Ecosystem (FiDLE) is designed to meet cross-center data management, advanced data science, and analytics platform needs. It serves to address challenges associated with interoperability, scalability, and machine learning availability by building up capabilities within several Enterprise Product Lines.
FISMA	Federal Information Security Modernization Act (FISMA) is a law that was enacted to establish a comprehensive framework for securing federal government information systems and data.
GovCloud	An isolated area within Amazon Web Services (AWS) designed to host sensitive data, regulated workloads, and address the most stringent U.S. government security and compliance requirements.
HHS	The U.S. Department of Health and Human Services.
Hybrid Environment	A combination of cloud and on-prem systems.

Term or Acronym	Definition or Explanation
IaaS	Infrastructure as a Service (IaaS) is one of the three primary service models in cloud computing, alongside PaaS and SaaS. IaaS provides users with virtualized computing resources over the internet, allowing them to access and manage fundamental infrastructure components without the need for physical hardware ownership or maintenance.
Improvement Opportunity	An opportunity to improve or make something better/more efficient, specifically a process or aspect of an organization that has the potential for enhancement or optimization.
IT Liaison	A person or job role at the FDA that serves as the bridge between enterprise IT services teams and centers and offices seeking IT solutions.
IT SME (Subject Matter Experts)	One of the three (3) major Cohort groups in this assessment. IT SME includes staff that own or oversee existing IT systems and architecture or with specific knowledge of FDA IT systems, architecture, records retention policies, and cybersecurity.
Legacy System(s)	Refers to outdated computing software or hardware that is still in use. Sometimes refers to the previous iteration of a solution.
Lift and Shift	The practice of migrating a system or application to a new location (physical or digital) while changing as little as possible in terms of capabilities and design.
MuleSoft	A tool used at the FDA to facilitate message routing among its systems in a hybrid multi-cloud architecture environment.
ODT	Office of Digital Transformation (ODT) is an enterprise level office at the FDA that provides the vision and leadership in information technology (IT), data, and cybersecurity needed to advance FDA's mission and strategic priorities.
OIMT	Office of Information Management and Technology (OIMT) is the FDA's premier IT organization, primarily serving to provide IT technologies and services to the FDA community.
On-prem	References IT infrastructure and applications residing on hardware located within a physical datacenter owned and operated by the FDA. For the purposes of this report "on-prem" mostly refers to the datacenters in the Ashburn Data Center and White Oak Data Center.
PaaS	Platform as a Service (PaaS) is one of the three (3) primary service models in cloud computing, alongside IaaS and SaaS. PaaS is cloud computing model that provides customers a complete cloud platform--hardware, software, and infrastructure for developing, running, and managing

Term or Acronym	Definition or Explanation
	applications without the cost, complexity, and inflexibility that often comes with building and maintaining that platform on-premises.
PAG	FDA's Project Advisory Group (PAG) is responsible for advising the Cloud Assessment Team on FDA specific technical architecture, security policies and potential stakeholders.
POC	Point Of Contact
Process Managers	One of the three (3) major Cohort groups in this assessment. Process Managers include Center and Office leadership (e.g., directors, assistant directors) and individuals involved in developing, managing, and optimizing application review processes.
SaaS	Software as a Service (SaaS) is one of the three (3) primary service models in cloud computing, alongside IaaS and PaaS. SaaS a cloud computing model where software applications are provided to users over the internet on a subscription basis. In this model, the software is hosted and maintained by the CSP, and users can access it through a web browser or application interface without the need to install or manage software locally on their decides.
SDLC	Software Development Life Cycle (SDLC) is a structured process that enables the production of high-quality, low-cost software, in the shortest possible production time.
Siloed Solutions	A system, process, or solution isolated from others, either physically or conceptually.
SOP	Standard Operating Procedure (SOP) is a fixed set of instructions for carrying out usually routine operations.
Third (3rd) Party	In terms of IT, a third party typically refers to other companies (other than the FDA in this context) that are contracted to provide services.
TIC	Trusted Internet Connection (TIC) is a federal cybersecurity initiative intended to enhance network and data security across the federal government.
Vendor	A person or company offering something for sale.