FDA
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ADMINISTRATION
OIMT | Office of Information Management and Technology
Information Technology Strategic Plan
2015-2018
2017 Update

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# MESSAGE FROM THE CIO

*Todd Simpson – FDA Chief Information Officer*

As we stay on course to enable the FDA to fulfill its mission of promoting and protecting the public health more securely, effectively and efficiently, we are pleased to present an updated IT Strategic Plan to reflect our progress, next steps and alignment with FDA priorities. In the last fifteen months OIMT has completed over 40% of the strategic milestones from the plan, continued to lower the IT cost per user and quickly addressed the information security concerns outlined by the GAO - already fully implementing 80 percent (12 of 15) of GAO's program recommendations, and 76 percent (126 of 166) of GAO's technical recommendations. This could not have been achieved without the strength and dedication of our employees who worked together tirelessly to support the FDA mission, while ensuring the protection of industry and public health information.

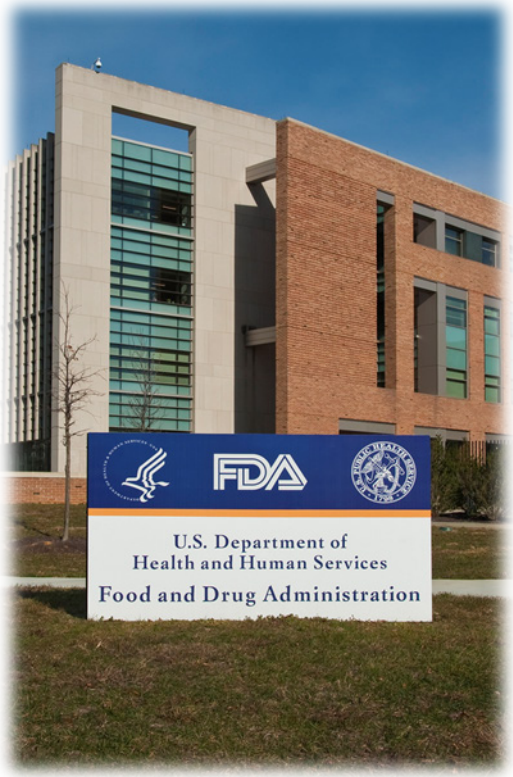
OIMT made significant progress under the *IT Strategic Plan*. The updated Plan incorporates IT priorities of the Centers as it continues to focus on the goals of strengthening our Cybersecurity program, compliance of key regulations and mandates, improving the quality of IT services and solutions and improving efficiency. The objectives and initiatives in the Plan directly support the goals and align to FDA's strategic priorities. Progress towards the Plan's goals and objectives will be monitored and evaluated by the OIMT Office of Enterprise Portfolio Management (OEPM) and through the balanced scorecard.

This Strategic Plan is the result of the extraordinary commitment and dedication of our team, and the partnership with the Centers. Increasing collaboration with the Centers and investment into our workforce are critical to the success of OIMT as we continue to look at opportunities for consolidation and expansion of our capabilities to meet future needs.

Todd Simpson
Chief Information Officer

# OIMT MISSION

The Office of Information Management and Technology (OIMT) manages information technology (IT) and related services including technical oversight of system development processes and policies and related governance activities. OIMT ensures that the Food and Drug Administration (FDA) has a robust IT foundation that enables interoperability across the agency and allows the development of enterprise wide systems necessary to meet the FDA's mission of promoting and protecting public health in an efficient, effective, productive and timely manner. OIMT strives to consistently meet the business needs of its customers, providing services that comply to Federal regulations and mandates, while adhering to the Agency's IT standards and policies.




The OIMT Strategic Plan establishes the goals, objectives and strategies to reinforce and support the mission of FDA - to protect the public health by ensuring the safety, effectiveness and security of human and veterinary drugs, biological products and medical devices, ensuring the safety of foods, cosmetics and radiation-emitting products; and regulating tobacco products. This document also provides the approach OIMT is taking to address the challenges of delivering IT services in a dynamic environment with new regulations and continuous advancements in science and technology.

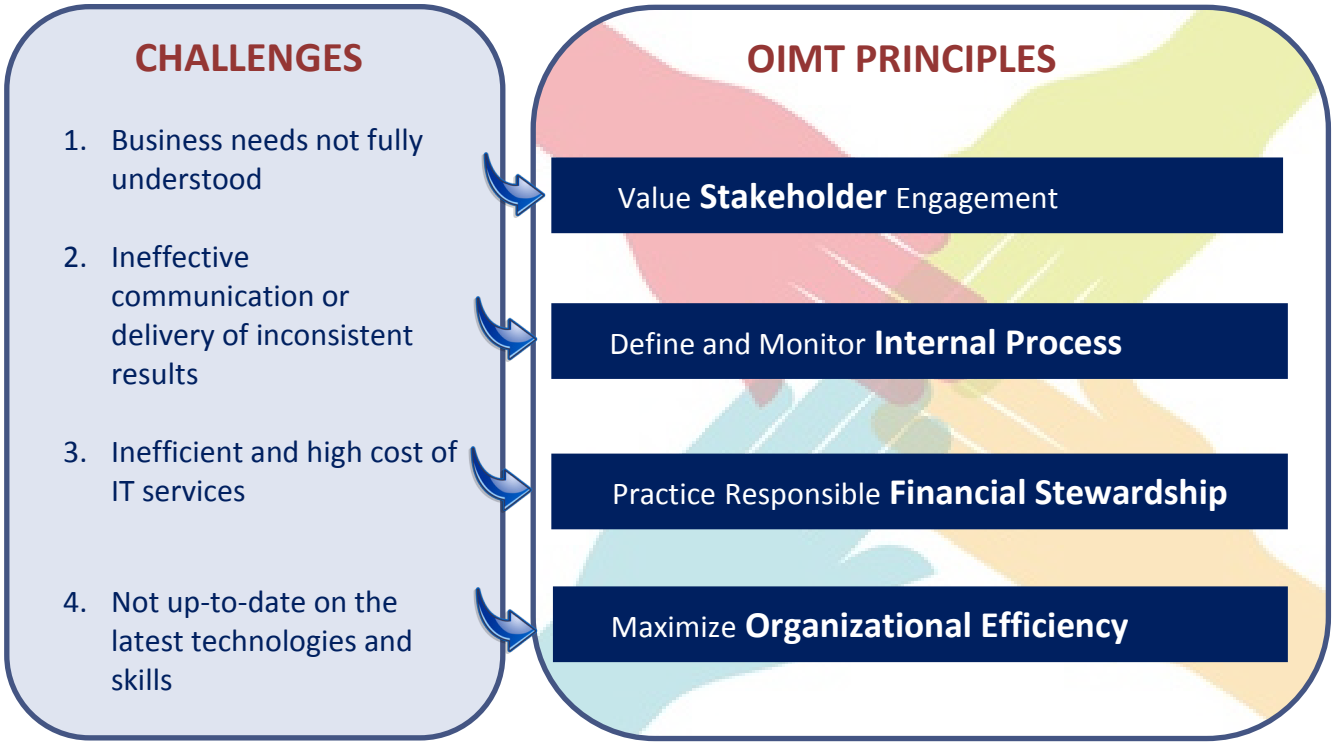
***OIMT Mission***

*To provide high quality, secure, and efficient IT solutions that enable the FDA to promote and protect the public health*

# GUIDING PRINCIPLES

The challenges that OIMT face are real. These include multiple fragmented environments, system duplication, a lack of defined interconnecting process, workflows and a mission aligned enterprise architecture. This has led to unpredictable outputs, increased complexity, a lack of standardization, role misalignment, and costly and unfocused system duplication.

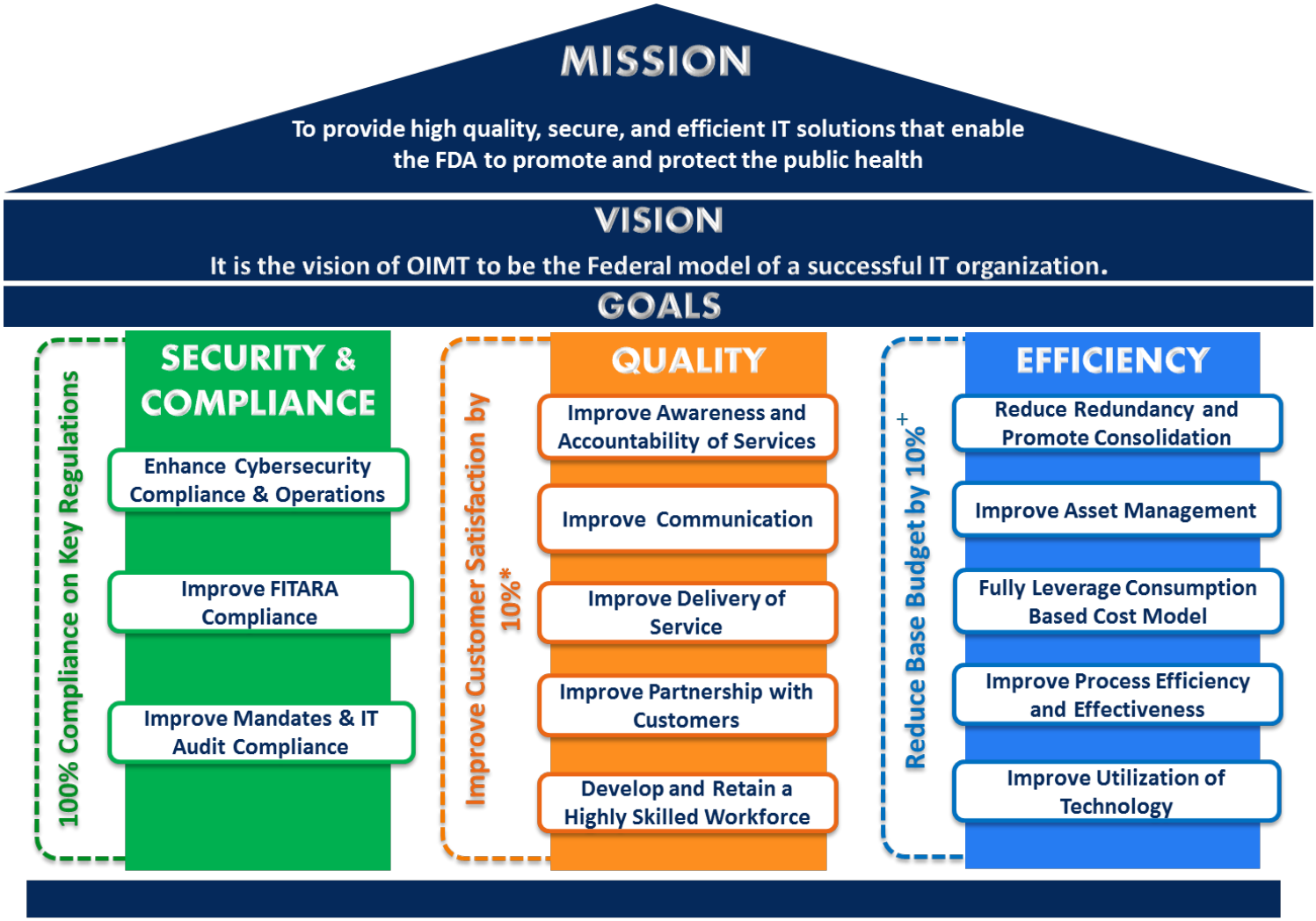
Both OIMT staff and the Centers recognize great strides over the past few years. OIMT recognizes that there is still much to be done. The following principles form the common themes that will guide OIMT to address the challenges and achieve the results set by the IT Strategic Goals and Objectives.



# GOALS AND OBJECTIVES

In adhering to the guiding principles, OIMT has identified three main results driven goals:

| | *Overall Goal* | *Performance Goal* *achieve by end of FY18* |
|---|---|---|
| ***Security & Compliance*** | Ensure the security, reliability, and accuracy, of the Agency's systems as required and in support of key regulations and mandates. | 100% compliance on key regulations |
| ***Quality*** | Deliver high quality IT products and services that are critical for the FDA to fulfill its mission, and in support of related administrative and operational needs. | Improve customer satisfaction by 10% (measured quarterly) |
| ***Efficiency*** | Provide IT systems and services in an efficient, effective, and timely manner. | Reduce base budget by 10% (cost per user) |




* Customer Satisfaction measured quarterly
\+ Based on Cost per User

# OIMT SUPPORTING FDA PRIORITIES

U.S. FOOD & DRUG ADMINISTRATION

**OIMT Strategic Plan 2015-2018**

**OIMT MISSION**

*Provide high quality, secure, and efficient IT solutions that enable the FDA to promote and protect the public health*

**OIMT VISION**

*To provide world-class technology services and be the Federal model of a successful IT organization*

| Strategic Goals | Key Outcomes | Enable FDA to |
|---|---|---|
| SECURITY & COMPLIANCE | • Regulatory Review and Scientific data and information are kept secure.<br>• FDA is able to continue its mission in the event of a disaster.<br>• Prevention of risk exposure and disruption to FDA's 300 systems/applications, and mobile devices.<br>• FDA mission is carried out with minimal interruption.<br>• User Fee programs are adequately supported. | • Continuously perform core capabilities required to carry out its mission in a secure environment with accuracy.<br>• Maintain public and industry confidence in FDA and the Government.<br>• Improve the predictability, consistency, transparency, and efficiency of the review process. |
| QUALITY | • A more collaborative and cooperative culture.<br>• Availability of Cloud services.<br>• Capability for High Performance Computing (HPC).<br>• Scientific computing needs are met – OIMT is able to support advanced computing needs.<br>• Field offices have improved data connection, enhancing and accelerating inspection processes.<br>• FDA has a modernized communication platform and can better engage and provide the public with safety and health information.<br>• FDA's IT infrastructure is able to accommodate growth of requirements; supporting advancements and innovation of regulatory science.<br>• Build, enhance, and maintain systems and applications that are mission-critical and enable FDA to perform its core capabilities.<br>• FDA users are able to perform duties using a mobile device; improving the effectiveness and efficiency of the inspection.<br>• Reduced duplication of efforts which allows for increased delivery of high value services and solutions. | • Increase regulatory science capacity to effectively evaluate products.<br>• Improve the predictability, consistency, transparency, and efficiency of the review process.<br>• Improve safety and health information provided to the public.<br>• Improve patient and provider access to benefit-risk information about FDA-regulated products.<br>• Reduce risks in manufacturing, production, and distribution of FDA-regulated products.<br>• Invest in infrastructure to enhance productivity and capabilities.<br>• Improve the overall operation and effectiveness of FDA. |
| EFFICIENCY | • FDA users will be able obtain IT services and solutions to common problems in one place.<br>• Sharing data across the agency will be easier; accelerating regulatory review , surveillance, and compliance enforcement processes.<br>• Key paper dependent business processes such as field inspections and sample collections, are automated.<br>• IT services are delivered more quickly and accurately.<br>• IT cost per user is decreased through process efficiencies and implementation of a central governance model for IT cost allocation.<br>• FDA is up-to-date with technological advancements and of industry standards .<br>• IT projects are aligned with FDA priorities. | • Strengthen detection and surveillance of problems with FDA-regulated products.<br>• Reduce risks in the manufacturing, production, and distribution of FDA-regulated products.<br>• Enhance oversight of FDA-regulated products.<br>• Improve the overall operation and effectiveness of FDA.<br>• Increase regulatory science capacity to effectively evaluate products. |

**In Support of Core Capabilities**

**Regulatory Review**

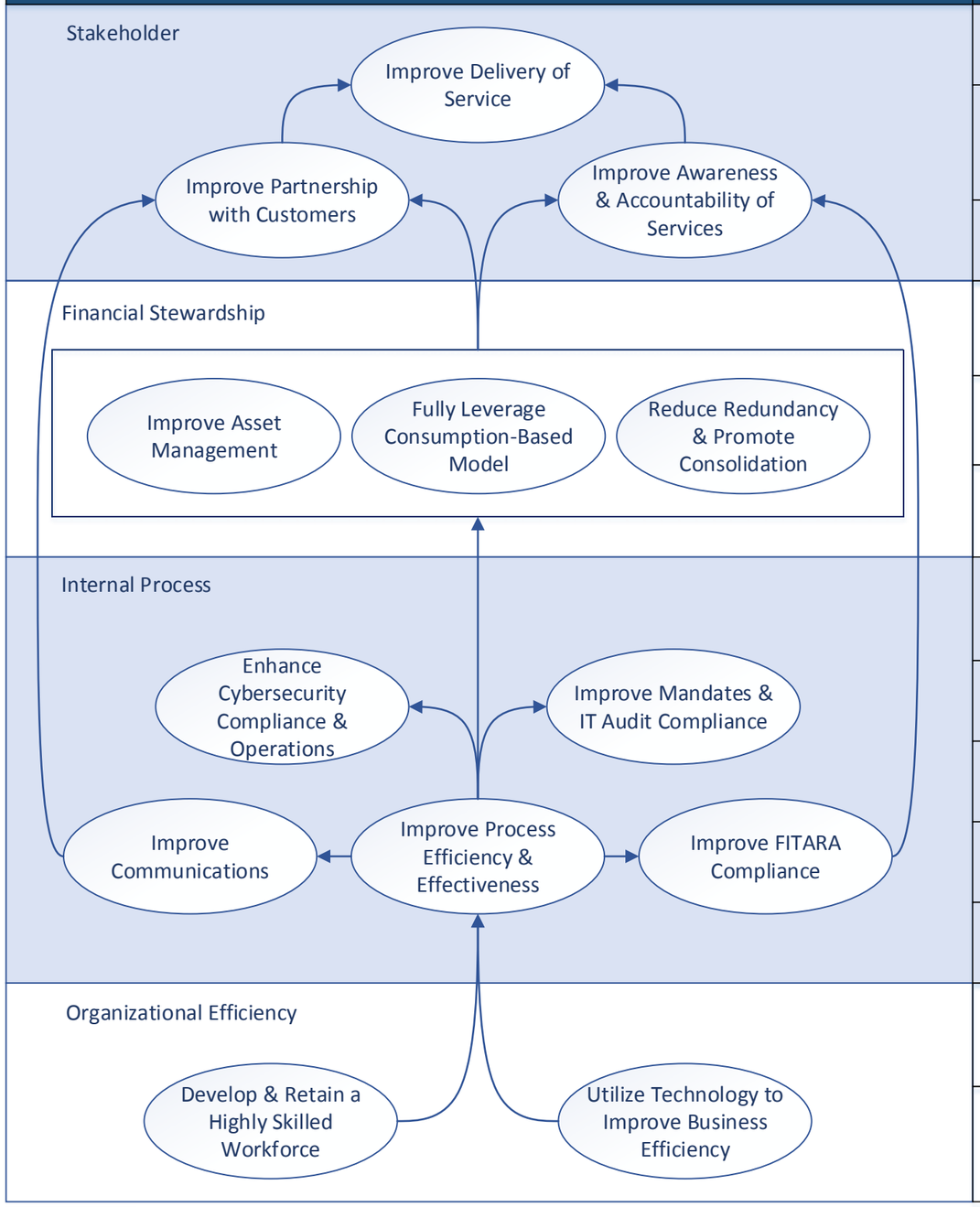
- Product Review & Approval
- Registration & Listing
- Post-Market Safety & Surveillance
- Emergency Response
- Compliance & Enforcement

**Scientific Operations**

- Laboratory Mgmnt. & Analysis
- Regulatory Science

**Enterprise Business**

- Administration
- Operations

| OIMT Balanced Scorecard | | | |
|---|---|---|---|
| **Mission:** To provide high quality, secure, and efficient IT solutions that enable the FDA to promote and protect the public health | | | |
| **Vision:** It is the vision of OIMT to be the Federal model of a successful IT organization. | | | |
| **Strategic Themes:**<br>Security & Compliance \| Quality \| Efficiency | | | |
| Strategy Map | Objectives | Measures | Targets |
|  | Improve Delivery of Service | • % of existing SLAs being met | >=80% |
| | Improve Partnership with Customers | • % of ADCIOs and CITLs who rate questions related to communication of IT Operations and Projects via a customer satisfaction survey as satisfactory | Increase 5% yearly |
| | Improve Awareness & Accountability of Services | • % of projects that follow the EPLC process | >=75% annually |
| | Improve Asset Management | • % of assets accounted for<br>• % of information collected through automated means | >=90%<br>>=60% |
| | Fully Leverage Consumption-Based Model | • % of OIMT services captured in the Cost Allocation Model | = 100% |
| | Reduce Redundancy & Promote Consolidation | • % reduction of base budget (cost per user)<br>• % of identified duplicate applications/systems decommissioned | >=10%<br>>=10% |
| | Enhance Cybersecurity Compliance & Operations | • % of FDA operational systems that are authorized and meet FISMA compliance requirements | = 100% |
| | Improve Mandates & IT Audit Compliance | • % of critical systems that have a disaster recovery strategy | =100% |
| | Improve Communications | • % of respondents who rate questions related to communcation of processes via a customer satisfaction survey as satisfactory | Increase 5% yearly |
| | Improve Process Efficiency & Effectiveness | • % of identified policies, processes, and workflows that are developed, approved and communicated | >=75% |
| | Improve FITARA Compliance | • % of major investments being managed by project managers in compliance with FDA FAC-P/PM requirements | =100% |
| | Develop & Retain a Highly Skilled Workforce | • % of staff attending role-based training | >=65% |
| | Utilize Technology to Improve Business Efficiency | • % of applications with automated deployments<br>• % of identified key paper dependent business processes that are automated | >=50%<br>>=50% |

# GOAL 1: SECURITY & COMPLIANCE

Ensure the security, reliability and accuracy, of the Agency's systems as required and in support of key regulations and mandates.

The Office of Information Management and Technology (OIMT) supports the FDA in fulfilling its mission with over 80 systems and a multitude of services dedicated to supporting the Agency's key functions such as product review and evaluation, compliance regulation and product safety monitoring. It is critical for OIMT to ensure the security, reliability and accuracy of these systems as required and in support of key regulations and mandates such as, but not limited to, the Federal Information Security Management Act (FISMA), and the Federal Information Technology Acquisition Reform Act (FITARA).

By ensuring the security of FDA's data and systems, OIMT is helping to maintain public confidence in the FDA and in our government.

**Performance Goal**

Reach 100% compliance on key regulations

**Objective 1.1:**
Enhance Cybersecurity compliance and operations

**Objective 1.2:**
Improve FITARA compliance

**Objective 1.3:**
Improve mandates & IT audit compliance

## **Objective 1.1:** Enhance Cybersecurity Compliance & Operations

The FDA Cybersecurity Program provides near real-time cybersecurity capabilities and risk management methodologies to protect sensitive data and information systems in support of the U.S. Food and Drug Administration's public health mission; and ensures security controls are appropriately applied to FDA systems for the protection of privacy and to ensure the confidentiality, integrity, and availability of information.

In support of this strategic plan, the FDA Cybersecurity Program will meet this objective by addressing the five strategic priorities:

Information Protection
Cyber, Threat and Vulnerability Management
IT and Cybersecurity Compliance
Center Engagement, Awareness, and Workforce Development
Workflow Standardization and Alignment

### Key Initiatives:

**1.1.1** Enhance and strengthen the FDA Cybersecurity Program to conduct highly effective incident response, insider threat detection, operational situational awareness, compliance, and to decrease the overall security risks to sensitive FDA information and IT infrastructure.

**1.1.2** Implement data loss prevention, multi-factor authentication, security incident/event management tools, and encryption at rest.

**1.1.3** Implement Continuous Diagnostics and Mitigation capabilities to identify cybersecurity risks on an ongoing basis and prioritize these risks based upon potential impacts.

**1.1.4** Develop, implement, and maintain cybersecurity risk management capabilities and methodologies in accordance with the Framework for Improving Critical Infrastructure Cybersecurity and NIST SP 800-37/ Guide for Applying the Risk Management Framework to Federal Information Systems.

**1.1.5** Ensure compliance with and enforcement of national, departmental, and agency cybersecurity regulations, standards, and policies that align with the Office of Management and Budget (OMB), Federal Information Security Management Act (FISMA), National Institute of Standards and Technology (NIST), Federal Risk and Authorization Management Program (FedRAMP), and Health and Human Services (HHS) requirements.

**1.1.6** Address recommendations made by the Government Accountability Office (GAO) audit and long standing FISMA findings, threats, vulnerabilities, risks, and weaknesses.

**1.1.7** Develop both a dynamic and static application security testing to allow system developers the ability to test their systems and applications through all phases of the lifecycle.

## Objective 1.2: Improve FITARA Compliance

**Key Initiatives:**

**1.2.1** Assess and implement FAC-P/PM strategy for major investments.

**1.2.2** Improve process for budget formulation and tracking.

**1.2.3** Develop strategy for software sourcing to enhance Agency-wide acquisition, shared use, and dissemination of software, as well as compliance with end user license agreements.

## Objective 1.3: Improve Mandates & IT Audit Compliance

**Key Initiatives:**

**1.3.1** Develop a framework for a records management strategy for mobile devices, including texts and voicemails.

**1.3.2** Develop a strategy that includes a disaster recovery solution that provides business continuity for critical applications and vital records.

**1.3.3** Develop a business continuity plan.

**1.3.4** Enhance and improve backup processes to ensure that OIMT can meet business needs to return to operations.

**1.3.5** Enhance the eDiscovery program.

**1.3.6** Develop and implement a strategy to support User Fee programs. This includes the following PDUFA VI committments:

a. By December 31, 2017, publish and maintain up-to-date documentation for the electronic submission process, including key electronic submission milestones and associated sponsor notifications. The description shall cover the complete process undergone by a submission from the completion of its upload to the Electronic System Gateway (ESG) through the time the submission is made available to the review team.

b. By December 31, 2017, publish and maintain up-to-date documentation for the electronic submissions rejection process, valisation criteria, and software names and versions for Electronic Common Document Technical Document (eCTD) validation and data validation tools.

c. Publish targets for and measure ESG availability overall (including scheduled downtime) and during business hours (8am to 8pm Eastern Time). ESG availability is defined as the ability for an external user to complete a submission from each entry point to its delivery to the appropriate FDA Center.

d. Post current ESG operational status on its public website.

e. Publish submission instructions to use in the event of an ESG service disruption.

f. By December 31, 2017, publish target time frames for the 1) expected submission upload duration(s) and 2) timeframe between key milestones and notifications as defined in (a) above.

g. By September 30, 2018, Implement the ability to communicate electronic submission milestone notifications, including final submission upload status (e.g., successfully processed or rejected), to sender/designated contact.

h. Provide expert technical support for electronic submissions to FDA review staff for submission navigation and troubleshooting.

i. For those systems that sponsors interact with directly, invite industry to provide feedback and/or participate in user acceptance testing in advance of implementing significant changes that impact industry's interaction with the system.

j. By December 31, 2017, document and implement a process to provide ample advance notification of systems and process changes commensurate with the complexity of the change and the impact to sponsors for ESG scheduled unavailability and user interface changes.

k. By December 31, 2017, post, at least annually, historic and current metrics on ESG performance in relation to published targets, characterizations and volume of submissions, and standards adoption and conformance.

l. Collaborate with Standards Development Organizations and stakeholders to ensure long-term sustainability of supported data standards.

m. Publish a data standards action plan updated at least quarterly.

n. Publish and maintain a current FDA Data Standards Catalog.

**1.3.7** Develop a strategy for data center optimization

# GOAL 2: QUALITY

Deliver high quality IT products and services that are critical for the FDA to fulfill its mission and in support of related administrative and operational needs.

In support of FDA's mission, OIMT is committed to improving our partnership with the Centers in order to drive awareness and accountability of our services, while delivering quality systems and services in support of FDA's priorities such as in the areas of cloud, mobility, scientific and high performance computing, and public communication. In addition, OIMT will improve the reliability of tools and systems needed to maintain and support the Agency's administrative and operational functions.

A high quality workforce will be needed to deliver high quality of services. OIMT will continue to develop and invest in our workforce to ensure current and future Agency needs are addressed at the highest level of quality possible.

**Performance Goal**

Improve customer satisfaction by 10% (measured quarterly)

**Objective 2.1:**
Improve awareness and accountability of services

**Objective 2.2:**
Improve communication

**Objective 2.3:**
Improve delivery of service

**Objective 2.4:**
Improve partnership with customers

**Objective 2.5:**
Develop and retain a highly skilled workforce

## **Objective 2.1:** Improve Awareness and Accountability of Services

**Key Initiatives:**

**2.1.1** Mature the Program Management Office by refining standard review and reporting procedures used to provide oversight for all IT projects and investments.

**2.1.2** Develop Service Level Agreements (SLAs) with metrics tracking to ensure accountability of services.

## **Objective 2.2:** Improve Communication

**Key Initiatives:**

2.2.1 Streamline communications within the organization and promote OIMT activities and accomplishments throughout the Agency.

2.2.2 Improve efficiency and frequency of communications with the Centers.

2.2.3 Develop a plan for modernizing the FDA's communication platform used to engage and provide the public of safety and health information.

2.2.4 Employ a balanced scorecard methodology to inform our customers about IT initiatives and on-going activities, and measure our adherence to the established SLAs and OLAs.

2.2.5 Enhance the centralized internal knowledgebase that documents IT related issues or problems, and how they are resolved.

## **Objective 2.3:** Improve Delivery of Service

**Key Initiatives:**

2.3.1 Improve unified communications for field offices.

2.3.2 Develop high speed connections to remote offices to facilitate data transfer.

2.3.3 Implement continuous service improvement processes (i.e., Service Level Agreements (SLAs) and Operation Level Agreements (OLAs)) to ensure that customers are provided services in a timely manner.

2.3.4 Enforce a governance model that drives quality, consistency and integrity into the service and project delivery processes.

2.3.5 Increase the number of projects to be reviewed through the quality review process to ensure that projects are within scope, on time, and on budget, and help mitigate high probability risks and high impact issues.

2.3.6 Develop a strategy to provide Software Defined Network.

2.3.7 Perform capacity management and IT forecasting to ensure that the IT infrastructure is able to meet anticipated business growth.

2.3.8 Utilize enterprise architecture methodologies to stabilize and modernize the infrastructure.

2.3.9 Develop a technology roadmap to modernize and more effectively plan for technology refresh.

2.3.10 Develop a strategy and implementation plan for application modernization.

2.3.11 Improve timely access to information and data to support the need for access to Agency data.

2.3.12 Develop, communicate, and implement a comprehensive, standardized mobility strategy.

2.3.13 Implement a comprehensive cloud strategy.

2.3.14 Integrate FDA's scientific computing program into the enterprise architecture, in order to meet advanced computing needs in support of the continuous advancement and evolution of Regulatory Science.

2.3.15 Continue to implement public and private Infrastructure as a Service (IaaS) to increase mission effectiveness and efficiency and meet OMB mandates.

2.3.16 Implement digitization project in order to reduce the physical document footprint in the field offices.

2.3.17 Develop a Master Data Management strategy to handle business data and Big Data requirements.

## **Objective 2.4:** Improve Partnership with Customers

### Key Initiatives:

2.4.1 Create an interactive self-help portal to allow users to identify IT solutions themselves.

2.4.2 Improve center engagement to address IT challenges to enable the centers to meet regulatory and compliance requirements.

## **Objective 2.5:** Develop and Retain a Highly Skilled Workforce

**Key Initiatives:**

2.5.1 Develop a career growth program that will provide transparent and clearly defined IT career paths with criteria for progression to the next level in both technical and leadership positions.

2.5.2 Develop talent retention, and succession planning.

2.5.3 Implement role-based training that focuses on specialized knowledge, skills, abilities, and performance.

2.5.4 Develop a mentoring program which will provide new hires with the opportunity to understand the complexities that exist within FDA, as well as have the opportunity for collaboration.

2.5.5 Right size the staff level and contractor support for cost savings and agility.

2.5.6 Perform an organization assessment and staff rationalization to identify and redeploy staff with the requisite skills.

2.5.7 Review Position Descriptions (PD) for updates, using common PDs where applicable (for similar positions).

# GOAL 3: EFFICIENCY

Provide IT systems and services in an efficient, effective, and timely manner.

OIMT maintains over 80 systems that support FDA's core, business management, and administrative capabilities. With rapid advancements in regulatory science and technology, governmental mandates and regulations, along with limited systems interoperability, OIMT has found it difficult to maintain the high volume of systems as the inventory continues to grow. There are multiple systems that:

1) Serve the same purpose, but were built for different Offices/Centers,
2) Maintain or store the same data or information, and
3) Are part of a work process but are not connected, requiring time consuming manual intervention, which in turn increases the risk for inaccurate or incomplete information being used for decision making.

Through consolidation of systems and reducing redundant applications, services and processes, support for these systems will be more manageable and will allow OIMT to better streamline our processes. This effort, along with improvements in asset management and increased systems interoperability, will allow the FDA to more efficiently and effectively work and share data while realizing long-term cost savings.

**Performance Goal**

Reduce base budget by 10% (cost per user)

**Objective 3.1:**
Reduce redundancy and promote consolidation

**Objective 3.2:**
Improve asset management

**Objective 3.3:**
Fully leverage consumption based cost model

**Objective 3.4:**
Improve process efficiency and effectiveness

**Objective 3.5:**
Utilize technology to improve business efficiency

## **Objective 3.1:** Reduce Redundancy and Promote Consolidation

**Key Initiatives:**

3.1.1 Streamline the OIMT procurement portfolio by continuing to collaborate with OAGS to perform strategic sourcing and category management.

3.1.2 Leverage enterprise architecture (EA) and business capability model to reduce infrastructure footprint.

3.1.3 Perform application rationalization to identify unused, redundant and out of date applications, and trim down the portfolio through application modernization and decommissioning.

3.1.4 Align the FDA IT Investment Review Board (ITIRB) decisions through early engagement to reduce redundant efforts.

3.1.5 Create a standardized framework for application development.

## **Objective 3.2:** Improve Asset Management

**Key Initiatives:**

3.2.1 Leverage enterprise architecture and asset management tools to collect a complete inventory of assets and applications to enhance asset management.

3.2.2 Evaluate available industry standard IT Service frameworks and develop and implement a strategy in support of managing, maintaining, and applying IT governance over applications and technologies at FDA.

## **Objective 3.3:** Fully Leverage Consumption-Based Cost Model

**Key Initiatives:**

3.3.1 Provide transparency into the costs and consumption of OIMT Services via the OIMT Enterprise Service Catalog and Cost Allocation Model.

3.3.2 Institutionalize a FDA IT Investment Review Board (ITIRB) to improve acquisition and fiscal management accountability for capital planning execution.

3.3.3 Leverage IT service management to implement governance model for IT cost allocation.

## **Objective 3.4:** Improve Process Efficiency and Effectiveness

**Key Initiatives:**

3.4.1 Enforce a project management methodology to standardize how IT projects are managed.

3.4.2 Implement quality management processes to baseline, and begin routine reporting on the performance of projects, key metrics.

3.4.3 Provide comprehensive oversight and guidance to IT personnel responsible for managing IT contracts and acquisitions. Collaborate across organizational boundaries with the Office of Acquisitions and Grants (OAGS) to make the acquisitions process efficient and ensure IT contracts are managed appropriately and to defined performance service levels.

3.4.4 Redeploy staff with the requisite skills based on organization assessment and staff rationalization.

3.4.5 Develop a role-based competency model to meet future business needs.

3.4.6 Assess and refine performance work plans to ensure that they accurately reflect the expected performance in order to ensure accountability.

3.4.7 Adopt ITIL methodologies for release management, configuration management, and unified monitoring.

3.4.8 Develop and publish the Service Catalog.

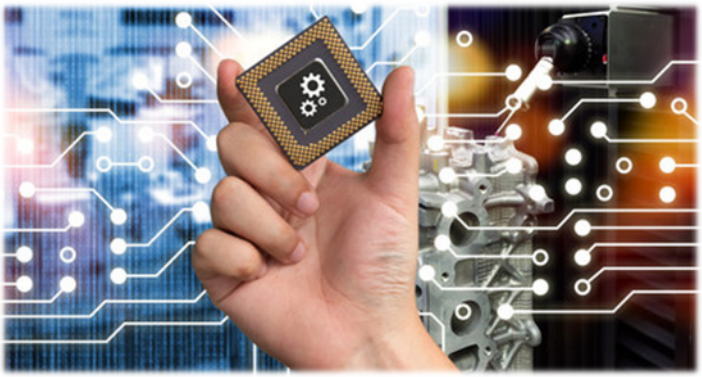
## **Objective 3.5:** Utilize Technology to Improve Business Efficiency

**Key Initiatives:**

3.5.1 Identify and automate key paper dependent business processes (ex. field inspections and sample collections).

3.5.2 Improve system inter-operability to allow for more efficient data sharing.

3.5.3 Expand and advance the Paperwork Reduction Act program.



# APPENDIX A: COMPLETED MILESTONES

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# APPENDIX B: STRATEGIC INITIATIVES

The following is the list of the strategic initiatives listed in priority order.

| PRIORITY | ID | INITIATIVE | STATUS |
|---|---|---|---|
| 1 | 3.4.7 | Adopt ITIL methodologies for release management, configuration management, and unified monitoring | In Progress |
| 2 | 2.5.3 | Implement role-based training that focuses on specialized knowledge, skills, abilities, and performance | In Progress |
| 3 | 2.3.9 | Develop a technology roadmap to modernize and more effectively plan for technology refresh | Closed |
| 4 | 3.1.3 | Perform application rationalization to identify unused, redundant and out of date applications, and trim down the portfolio through application modernization and decommissioning | In Progress |
| 5 | 2.4.2 | Improve center engagement to address IT challenges to enable the centers to meet regulatory and compliance requirements | In Progress |
| 6 | 1.2.1 | Assess and implement FAC-P/PM strategy for major investments | In Progress |
| 7 | 1.2.2 | Improve process for budget formulation and tracking | In Progress |
| 8 | 1.1.1 | Enhance and strengthen the FDA Cybersecurity Program to conduct highly effective incident response, insider threat detection, operational situational awareness, compliance, and to decrease the overall security risks to sensitive FDA information | In Progress |
| 9 | 1.1.2 | Implement data loss prevention, multi-factor authentication, security incident/event management tools, and encryption at rest | In Progress |
| 10 | 1.1.5 | Ensure compliance with and enforce national, departmental, and agency cybersecurity regulations, standards, and policies that align with OMB, FISMA, NIST, FedRAMP, and HHS requirements. | In Progress |
| 11 | 1.3.6 | Develop and implement a strategy to support User Fee programs | In Progress |
| 12 | 1.2.3 | Develop strategy for software sourcing to enhance Agency-wide acquisition, shared use, and dissemination of software, as well as compliance with end user license agreements | Closed |
| 13 | 3.3.2 | Institutionalize a FDA IT Investment Review Board (ITIRB) to improve acquisition and fiscal management accountability for capital planning execution | Open |
| 14 | 3.4.1 | Enforce a project management methodology to standardize how IT projects are managed | In Progress |
| 15 | 2.3.17 | Develop a Master Data Management strategy to handle business data and Big Data requirements | In Progress |
| 16 | 2.5.2 | Develop talent retention, and succession planning | Closed |
| 17 | 2.5.6 | Perform an organization assessment and staff rationalization to identify and redeploy staff with the requisite skills | In Progress |
| 18 | 3.3.3 | Leverage IT service management to implement governance model for IT cost allocation | Closed |
| 19 | 3.1.1 | Streamline the OIMT procurement portfolio by continuing to collaborate with OAGS to perform strategic sourcing and category management | In Progress |
| 20 | 2.5.1 | Develop a career growth program that will provide transparent and clearly defined IT career paths with criteria for progression to the next level in both technical and leadership positions | In Progress |
| 21 | 3.4.3 | Provide comprehensive oversight and guidance to IT personnel responsible for managing IT contracts and acquisitions | Closed |
| 22 | 3.3.1 | Provide transparency into the costs and consumption of OIMT Services via the OIMT Enterprise Service Catalog and Cost Allocation Model | Closed |

| INITIATIVE PRIORITY | ID | INITIATIVE | STATUS |
|---|---|---|---|
| 23 | 2.2.1 | Streamline communications within the organization and promote OIMT activities and accomplishments throughout the Agency | Closed |
| 24 | 1.3.2 | Develop a strategy that includes a disaster recovery solution that provides business continuity for critical applications and vital records | Closed |
| 25 | 1.3.3 | Develop a business continuity plan | In Progress |
| 26 | 1.3.4 | Enhance and improve backup processes to ensure that OIMT can meet business needs to return to operations | In Progress |
| 27 | 1.1.3 | Implement Continuous Diagnostics and Mitigation capabilities to identify cybersecurity risks on an ongoing basis and prioritize these risks based upon potential impacts | In Progress |
| 28 | 2.2.3 | Develop a plan for modernizing the FDA's communication platform used to engage and provide the public of safety and health information | Closed |
| 29 | 1.1.4 | Develop, implement, and maintain cybersecurity risk management capabilities and methodologies in accordance with the Framework for Improving Critical Infrastructure Cybersecurity and NIST SP 800-37/ Guide for Applying the Risk Management Framework | Closed |
| 30 | 1.1.6 | Address recommendations made by the Government Accountability Office (GAO) audit and long standing FISMA findings, threats, vulnerabilities, risks, and weaknesses | In Progress |
| 31 | 2.3.4 | Enforce a governance model that drives quality, consistency and integrity into the service and project delivery processes | In Progress |
| 32 | 1.3.7 | Develop a strategy for data center optimization | In Progress |
| 33 | 2.3.10 | Develop a strategy and implementation plan for application modernization | Closed |
| 34 | 2.5.7 | Review Position Descriptions (PD) for updates, using common PDs where applicable (for similar positions) | In Progress |
| 35 | 2.3.7 | Perform capacity management and IT forecasting to ensure that the IT infrastructure is able to meet anticipated business growth | In Progress |
| 36 | 1.3.1 | Develop a framework for a records management strategy for mobile devices, including texts and voicemails | Open |
| 37 | 3.1.5 | Create a standardized framework for application development | Closed |
| 38 | 1.1.7 | Develop both a dynamic and static application security testing to allow system developers the ability to test their systems and applications through all phases of the lifecycle | In Progress |
| 39 | 3.1.4 | Align the FDA IT Investment Review Board (ITIRB) decisions through early engagement to reduce redundant efforts | Open |
| 40 | 3.2.2 | Evaluate available industry standard IT Service frameworks and develop and implement a strategy in support of managing, maintaining, and applying IT governance over applications and technologies at FDA | In Progress |
| 41 | 2.3.11 | Improve timely access to information and data to support the need for access to Agency data | In Progress |
| 42 | 2.3.14 | Integrate FDA's scientific computing program into the enterprise architecture, in order to meet advanced computing needs in support of the continuous advancement of Regulatory Science | In Progress |
| 43 | 2.1.1 | Mature the Program Management Office by refining standard review and reporting procedures used to provide oversight for all IT projects and investments | In Progress |
| 44 | 2.1.2 | Develop Service Level Agreements (SLAs) with metrics tracking to ensure accountability of services | Closed |
| 45 | 2.3.13 | Implement a comprehensive cloud strategy | In Progress |
| 46 | 3.4.6 | Assess and refine performance work plans to ensure that they accurately reflect the expected performance in order to ensure accountability | In Progress |
| 47 | 3.4.2 | Implement quality management processes to baseline, and begin routine reporting on the performance of projects, key metrics | Closed |

| INITIATIVE PRIORITY | ID | INITIATIVE | STATUS |
|---|---|---|---|
| 48 | 1.3.5 | Enhance the eDiscovery program. | Open |
| 49 | 2.3.3 | Implement continuous service improvement processes (i.e., Service Level Agreements (SLAs) and Operation Level Agreements (OLAs)) to ensure that customers are provided services in a timely manner | In Progress |
| 50 | 2.3.15 | Continue to implement public and private Infrastructure as a Service (IaaS) to increase mission effectiveness and efficiency and meet OMB mandates | In Progress |
| 51 | 3.4.8 | Develop and publish the Service Catalog | Closed |
| 52 | 2.3.8 | Utilize enterprise architecture methodologies to stabilize and modernize the infrastructure | Closed |
| 53 | 3.5.3 | Expand and advance the Paperwork Reuction Act program. | In Progress |
| 53 | 2.3.12 | Develop, communicate, and implement a comprehensive, standardized mobility strategy. | In Progress |
| 55 | 2.2.4 | Employ a balanced scorecard methodology to inform our customers about IT initiatives and on-going activities, and measure our adherence. | Closed |
| 56 | 2.4.1 | Create an interactive self-help portal to allow users to identify IT solutions themselves | Closed |
| 57 | 2.5.4 | Develop a mentoring program which will provide new hires with the opportunity to understand the complexities that exist within the FDA, as well as have the opportunity for collaboration | Closed |
| 58 | 3.5.1 | Identify and automate key paper dependent business processes (ex. field inspections and sample collections) | In Progress |
| 59 | 3.5.2 | Improve system inter-operability to allow for more efficient data sharing | Open |
| 60 | 2.2.2 | Improve efficiency and frequency of communications with the Centers | In Progress |
| 61 | 2.3.16 | Implement digitization project in order to reduce the physical document footprint in the field offices | Open |
| 62 | 3.4.4 | Redeploy staff with the requisite skills based on organization assessment and staff rationalization | In Progress |
| 63 | 3.4.5 | Develop a role-based competency model to meet future business needs | In Progress |
| 64 | 2.3.2 | Develop high speed connections to remote offices to facilitate data transfer | In Progress |
| 65 | 2.2.5 | Enhance the centralized internal knowledgebase that documents IT related issues or problems, and how they are resolved | Closed |
| 66 | 2.3.6 | Develop a strategy to provide Software Defined Network | In Progress |
| 67 | 2.3.5 | Increase the number of projects to be reviewed through the quality review process to ensure that projects are within scope, on time, and on budget, and help mitigate high probability risks and high impact issues | In Progress |
| 68 | 2.3.1 | Improve unified communications for field offices | In Progress |
| 69 | 2.5.5 | Right size the staff level and contractor support for cost savings and agility | In Progress |
| 70 | 3.2.1 | Leverage enterprise architecture and asset management tools to collect a complete inventory of assets and applications to enhance asset management | In Progress |
| 71 | 3.1.2 | Leverage enterprise architecture (EA) and business capability model to reduce infrastructure footprint | In Progress |

# APPENDIX C: OIMT SUPPORTS FDA GOALS & OBJECTIVES

| FDA Strategic Goals and Objectives | | OIMT Objectives & Initiatives: Enhance Cybersecurity Compliance & Operations | Improve FITARA Compliance | Improve Mandates & IT Audit Compliance | Improve Awareness & Accountability of Services | Improve Communication | Improve Delivery of Service | Improve Partnership with Customers | Develop & Retain a Highly Skilled Workforce | Reduce Redundancy & Promote Consolidation | Improve Asset Management | Fully Leverage Consumption-Based Cost Model | Improve Process Efficiency & Effectiveness | Utilize Technology to Improve Business Efficiency |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Enhance Oversight of FDA-Regulated Products** | | **Security & Compliance** | | | | | **Quality** | | | | | **Efficiency** | | |
| 1.1 | Increase the use of regulatory science to inform standards development, analysis, and decision-making | | | 1.3.6 | | | 2.3.11 2.3.15<br>2.3.14 2.3.17 | | | | | | | 3.5.2 |
| 1.2 | Reduce risks in the manufacturing, production, and distribution of FDA-regulated products | 1.1.1 | | 1.3.2 1.3.4<br>1.3.3 1.3.6 | | | 2.3.11 2.3.16<br>2.3.15 2.3.17 | | | | | | | 3.5.1<br>3.5.2 |
| 1.3 | Strengthen detection and surveillance of problems with FDA-regulated products | 1.1.1 | | 1.3.2 1.3.4<br>1.3.3 1.3.6 | | | 2.3.1 2.3.16<br>2.3.2 2.3.17<br>2.3.15 | | | | | | | 3.5.1<br>3.5.2<br>3.5.3 |
| 1.4 | Improve response to identified and emerging problems with FDA regulated product | 1.1.1 | | 1.3.2 1.3.4<br>1.3.3 1.3.6 | | | 2.3.1 2.3.16<br>2.3.2 2.3.17<br>2.3.15 | | | | | | | 3.5.1<br>3.5.2 |
| **Improve and Safeguard Access to FDA-Regulated Products to Benefit Health** | | | | | | | | | | | | | | |
| 2.1 | Increase regulatory science capacity to effectively evaluate products | | | 1.3.6 | | | 2.3.11 2.3.15<br>2.3.14 2.3.17 | | | | | | | 3.5.2 |
| 2.2 | Improve the effectiveness of the product development process | | | 1.3.6 | | | 2.3.11<br>2.3.15<br>2.3.17 | | | | | | | 3.5.2 |
| 2.3 | Improve the predictability, consistency, transparency, and efficiency of the review process | | | 1.3.2 1.3.4<br>1.3.3 1.3.6 | | | 2.3.15<br>2.3.17 | | | | | | | 3.5.2 |
| **Promote Better Informed Decisions About the us e of FDA-Regulated Products** | | | | | | | | | | | | | | |
| 3.1 | Strengthen social and behavioral science to help patients, consumers, and professionals make informed decisions about regulated products | | | | | 2.2.3 | 2.3.15<br>2.3.17 | | | | | | | 3.5.2 |
| 3.2 | Improve patient and providers access to benefit–risk information about FDA-regulated products | | | | | 2.2.3 | 2.3.11<br>2.3.15<br>2.3.17 | | | | | | | 3.5.2 |
| 3.3 | Improve safety and health information provided to the public | 1.1.1 | | | | 2.2.3 | 2.3.15<br>2.3.17 | | | | | | | 3.5.2 |
| **Strengthen Organizational Excellence and Accountability** | | | | | | | | | | | | | | |
| 4.1 | Recruit, develop, retain, and strategically manage a world-class workforce | | 1.2.1 | 1.3.5 | | | | | 2.5.1 2.5.5<br>2.5.2 2.5.6<br>2.5.3 2.5.7<br>2.5.4 | | | | | |
| 4.2 | Improve the overall operation and effectiveness of FDA | 1.1.1 1.1.4<br>1.1.2 1.1.7<br>1.1.3 | 1.2.2<br>1.2.3 | 1.3.1 1.3.4<br>1.3.2 1.3.5<br>1.3.3 1.3.7 | 2.1.1<br>2.1.2 | 2.2.1 2.2.4<br>2.2.2 2.2.5 | 2.3.3 2.3.6<br>2.3.4 2.3.12<br>2.3.5 2.3.13 | 2.4.1<br>2.4.2 | 2.5.2<br>2.5.5<br>2.5.6 | 3.1.1 3.1.4<br>3.1.2 3.1.5<br>3.1.3 | 3.2.1<br>3.2.2 | 3.3.1<br>3.3.2<br>3.3.3 | 3.4.1 3.4.5<br>3.4.2 3.4.6<br>3.4.3 3.4.7<br>3.4.4 3.4.8 | 3.5.1<br>3.5.2 |
| 4.3 | Invest in infrastructure to enhance productivity and capabilities | 1.1.1<br>1.1.3<br>1.1.4 | | 1.3.5 | | | 2.3.7 2.3.13<br>2.3.8 2.3.14<br>2.3.9 2.3.17<br>2.3.12 | | | | | | | |