ESG Next Generation: Developing Enterprise Capabilities through ESG Modernization
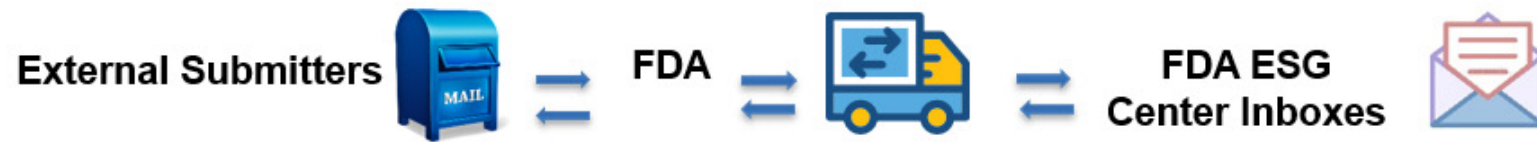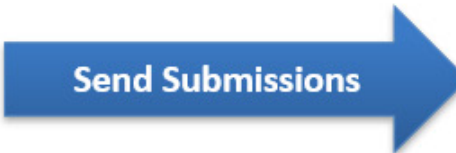
December 4, 2023

Agenda

1. ESG Background
2. ESG Next Generation Vision
3. Modernize Enterprise Services & Capabilities through ESG NextGen
   A. Increase Business Alignment
   B. Scale Operations
   C. Increase Digital Maturity
   D. Improve Customer Experience
   E. Modernize FDA Cybersecurity Defenses
   F. Reduce Technology Debt
4. Summary
5. Q's and A's

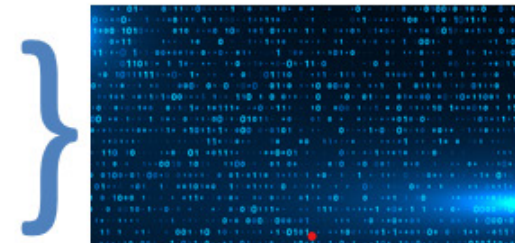FDA Digital Transformation Symposium

Background – ESG High Level Overview

External Submitters → FDA → FDA ESG Center Inboxes

Industry Submitter

Send Submissions →

← **Receive Receipt / ACK**

ESG
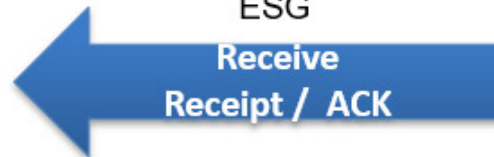
Downstream Systems
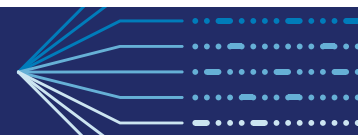
ESG NextGen Vision
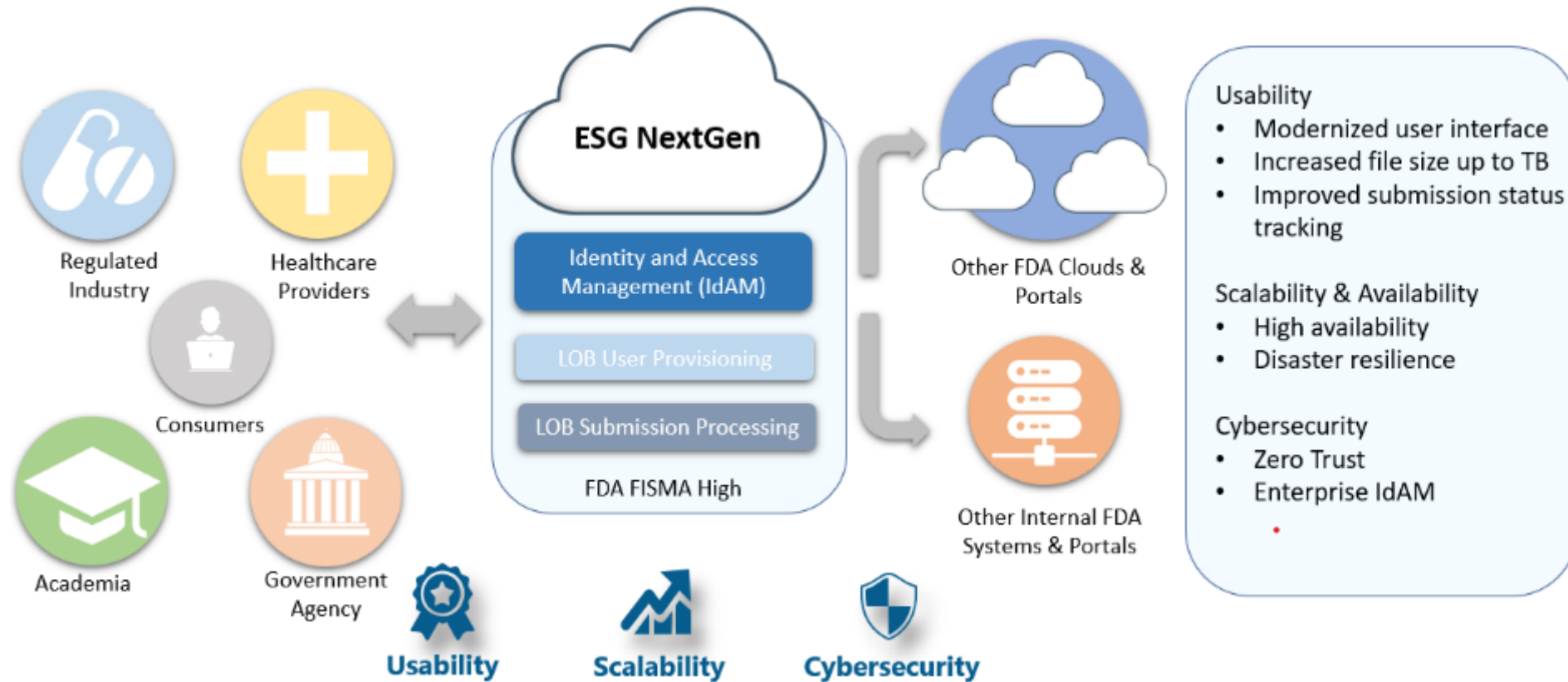
Increase Business Alignment

PDUFA/BSUFA Commitments

- Cloud
- Data Bandwidth
- IDAM

FDA Technology/ Strategic Plans

- Cloud Strategy
- Improved data exchange methods (API)
- Implement strong Identify principal and MFA tools

ESG NextGen Capabilities

- AWS FedRAMP High
- APIs for submission / data exchange
- Large submissions (1 TB)
- Integrated IDAM & MFA

Scale Operations

As-Is:

- Scalability is difficult and expensive to achieve under Hybrid Cloud infrastructure

- Does not align well with FDA's Modernization Strategy

<u>To be:</u>

- Cloud capabilities and scalability align to FDA's Modernization Strategy

- Provide flexibility for responding to unexpected influx of data/submissions

- Ability to react at a faster rate and lower cost

Increase Digital Maturity

Define digital maturity

Assess the current state

Identify a gap

Get buy-in from leadership and stakeholders

Develop a road map

Implement the model

Continuously assess the model

Achieving Digital Maturity

Improve Customer Experience

|	**Current State**	**Future State**
User Account Management	• Test then Production account • Long turnaround time for account creation • Lack of enterprise ICAM solution	• Comprehensive account provisioning workflow • Direct production acount creation • Federated ICAM
Package Preparation	• Client-side software installation required • Download and installation may be blocked by company security policy • No auto-update if FDA changes form(s)	• Web-based, step-by-step submission preparation • In-page file upload • File size-based submission workflow
File Submission	• Require digital certificate • No large file submission capability • Lack of transparent submission tracking • No integration with other FDA Center portals	• eSignature to replace digital certificate • Improved file upload performance • Unified submission portal with status/tracking • API service
Communication	• One-way outbound notifications via acknowledgement	• Secure two-way communication channel • Broadcast capability • Intelligent chatbot

Modernize FDA Cybersecurity Defense

- Unified submission portal – reducing number of intake portals reduces the risk of security vulnerabilities and threats

- Enterprise, Identity, Credential and Access Management (ICAM) Solution
  - Modernize the FDA's IT infrastructure to protect against threats, protect sensitive data, provide user and access provisioning and enable digital transformation at a faster rate
  - Complies with Federal Cybersecurity mandates
  - Solution for Multi-Factor Authentication (MFA) and Single Sign-On (SSO) capability
  - Enterprise solution standardize security implementation and reduces costly siloed Identity and Access Management (IDAM) solutions

Reduce Technology Debt
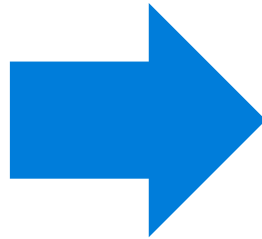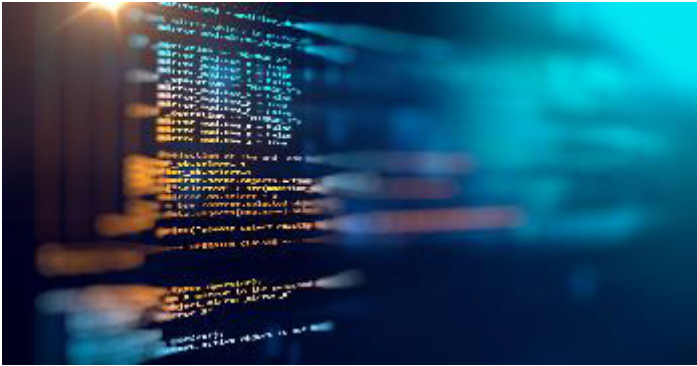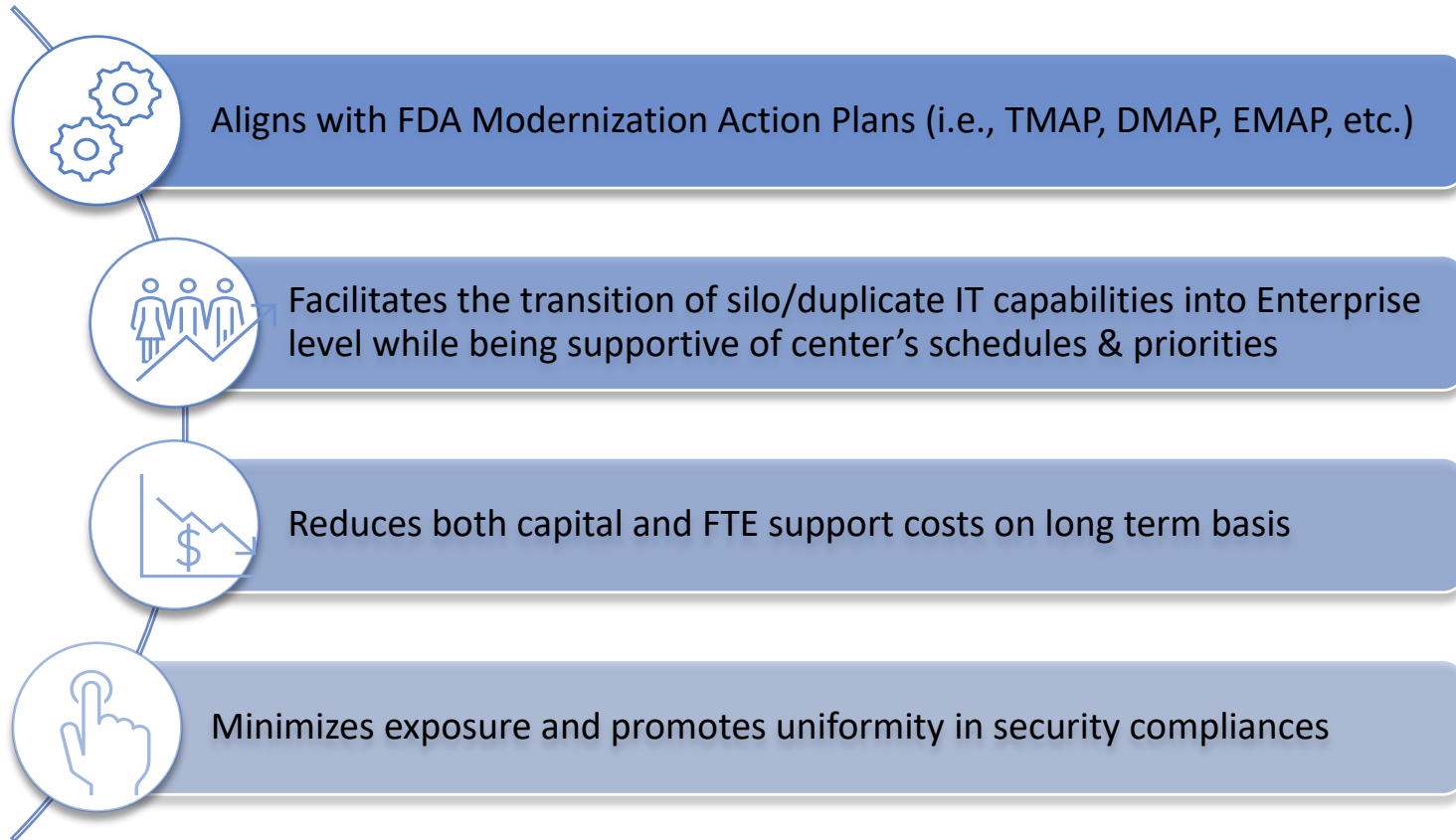

Current State – ESG

- Building custom code on top of COTS to address additional business needs
- Developing work around or short-term solutions to address deficiencies
- Greatly limit the ability to enhance functionality to meet the changing needs of the business
- Legacy technology
- OS Dependency (i.e. Windows Based PC)
- Lacks security standard integration

- Future State – ESG NextGen
  - Aligns with the latest FDA IT Strategic Plan
  - Implement a web-based solution to provide a more enhanced user experience
  - Leverages modern software development and cloud-based technologies
  - Enterprise IDAM solution
  - IT solution is device independent

Summary – Benefits of ESG NextGen

Aligns with FDA Modernization Action Plans (i.e., TMAP, DMAP, EMAP, etc.)

Facilitates the transition of silo/duplicate IT capabilities into Enterprise level while being supportive of center's schedules & priorities

Reduces both capital and FTE support costs on long term basis

Minimizes exposure and promotes uniformity in security compliances

Thank you!

Questions?