Electronic Submission Gateway (ESG): The Road to Modernization

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Agenda

- What is ESG?
- How Does ESG Work?
- Who Receives ESG Submissions?
- ESG & Industry Collaboration
- ESG Growth
- Recent ESG Enhancements
- Going Green
- Modernization
- ESG Next Gen
- Key Take Aways & Questions

What is ESG?

Learn about what ESG is

ESG is…

- The Food and Drug Administration (FDA) Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions. The FDA ESG enables the secure submission of premarket and postmarket regulatory information for review.
- The FDA ESG is the central transmission point for sending information electronically to the FDA. Within that context, the FDA ESG is a conduit along which submissions travel to reach the proper FDA Center or Office.

How Does ESG Work?

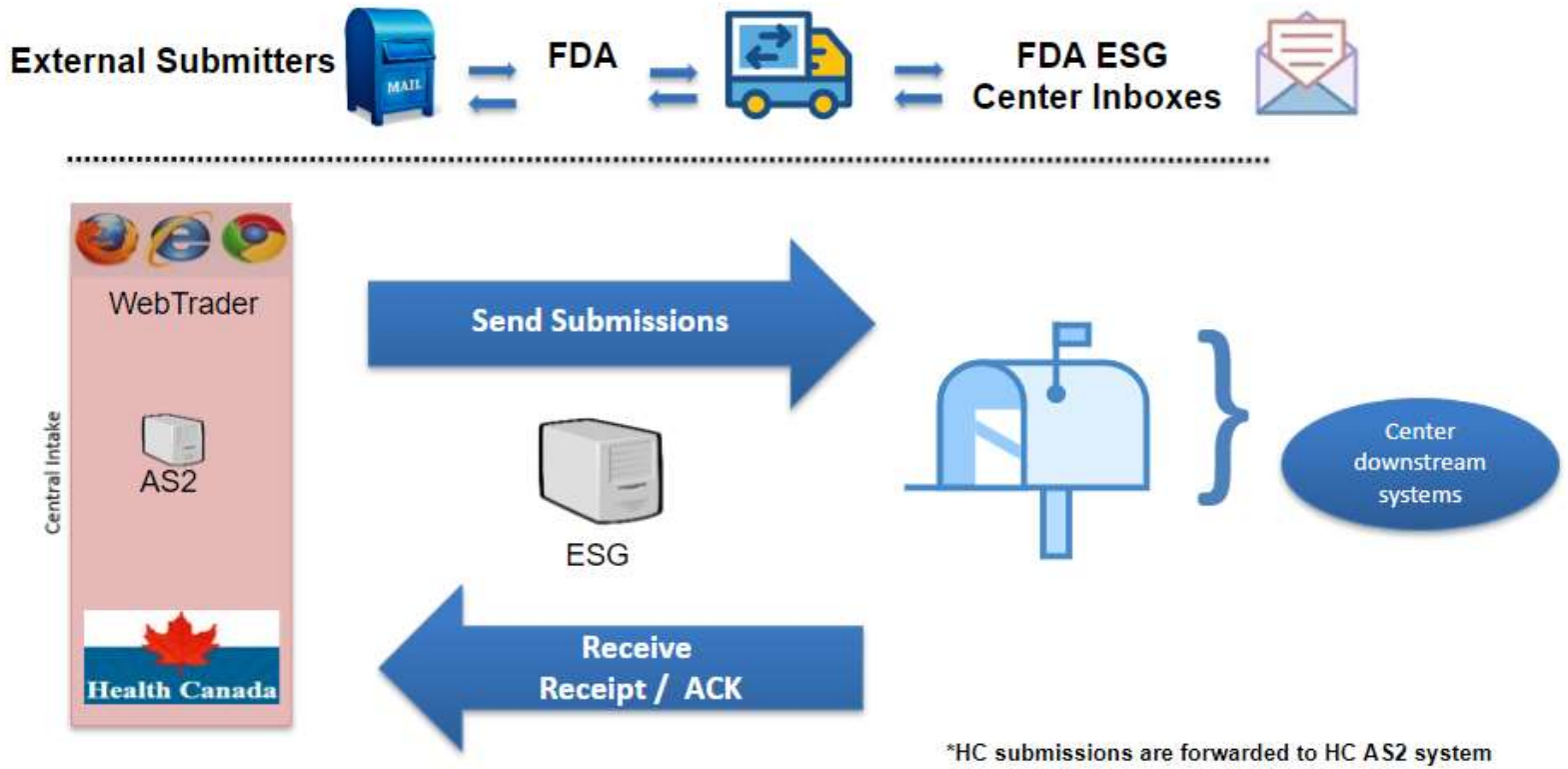
Learn how submissions are sent and received through ESG

How ESG Works…

1. User sends single file or folder submission to FDA via HTTPs.
2. ESG receives the submission and assigns a unique ID.
3. FDA ESG sends a Receipt to the submitter.
4. The submission is automatically transferred to the Center's Inbox.
5. A Center Acknowledgement is automatically generated and sent to the submitter via the FDA ESG.
6. The Center validates and processes the submission by accessing Center's Inbox.

For more information on acknowledgements can be found here: https://www.fda.gov/industry/about-esg/submission-acknowledgements

ESG Today


External Submitters
FDA
FDA ESG
Center Inboxes
WebTrader
AS2
Central Intake
Health Canada
Send Submissions
ESG
Receive
Receipt / ACK
Center
downstream
systems
*HC submissions are forwarded to HC AS2 system

How Do User Send Submissions

- WebTrader:

  A web-based interface (compatible with Windows OS) which requires a client to send documents and receive receipts and acknowledgments from the FDA. The WebTrader application makes communication with the FDA simple, cost-effective, and time-independent. All Submissions are signed using PKI certificates.

- AS2 (System-to-System):

  Industry Partners have the option to access the Gateway via system-to-system communication. System-to-system communication (often referred to as an AS2 Account) provides an automated connection to the FDA for submissions, receipts and acknowledgments. The system-to-system communication requires server(s) and software from Industry Partners. All Submissions are signed using PKI certificates.

Challenge Question #1

- Which of the following statements is NOT true?

A. ESG opens the submission file and reviews content for accuracy

B. ESG delivers the submission file to the FDA Center without opening or reviewing content.

C. ESG sends a receipt to the submitter to acknowledge the file has been received

Who Receives ESG Submissions

Learn which centers, offices and external partners receive ESG submissions

FDA Centers/Offices Receiving ESG Submissions

- Center of Veterinary Medicine (CVM)
- Center for Biologics Evaluation & Research (CBER)
- Center For Drug Evaluation and Research (CDER)
- Center for Food Safety and Applied Nutrition (CFSAN)
- Center for Devices and Radiological Heath (CDRH)
- Center for Tobacco Products (CTP)
- Health Canada (HC)
- Office of Regulatory Affairs (ORA)
- Office of the Commissioner (OC)

More information on the submission types can be found here: https://www.fda.gov/media/158183/download

ESG Industry Collaboration

Learn how ESG and Industry communicate

ESG's Collaboration with Industry

- Per Prescription Drug User Fee Act (PDUFA): FDA and industry will collaborate to plan and conduct meetings, review initiatives, and engage industry to provide feedback and/or participate in pilot testing prior to implementing significant changes that impact industry's interaction with the ESG. Annually, FDA leadership and PDUFA IT leadership will review initiatives and provide opportunity for Industry input.

Industry & Collaboration Cont.

- Continue to Participate in PDUFA Quarterly Industry meetings
- Continue to Participate in FDA and PDUFA leadership meetings
- Continue collaborative activities with Industry for impactful system and software changes

ESG Growth

Learn how ESG has grown from 2015 - Now

ESG Growth By Year

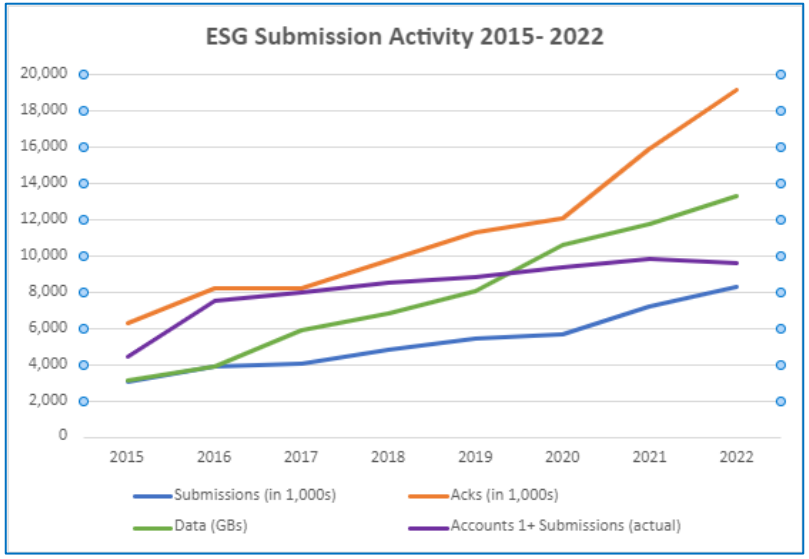
Total submissions:

2015	2016	2017	2018	2019	2020	2021	2022
3,100,970	3,895,669	4,055,342	4,841,844	5,428,492	5,728,006	7,258,031	8,350,467

Total transactions:

2015	2016	2017	2018	2019	2020	2021	2022
9,209,782	12,082,860	12,333,127	14,596,282	16,898,047	17,917,796	23,218,281	27,528,327

Average Annual Growth 2015 - 2022	
Submissions	15%
Acknowledgments	18%
Data	24%
Accounts	14%



Referenced from Submission Statistics | FDA

Recent ESG Enhancements

ESG Enhancements 2022 - 2023

ESG Enhancements 2022

- *Account Portal 1.0 and Submission Virus Scanning*
- Account Portal 1.0 Implemented in August 2022
  - Deliver new front end portal - enhances WebTrader user experience and automates the onboarding account management process; enables WebTrader account holder to use self service features
  - Benefit: Provides self-service features which allows users to easily navigate the account creation process, update passwords and digital certificates, and upload mandatory non-repudiation letters. The Account Portal also adds role-based functions (i.e. power users) to manage specific account items for their company and conduct company submission searches. The Account Portal system will also auto-promote accounts from the ESG Pre-Prod environment to Production upon Center approval, which will help to reduce onboarding time.
- Submission Virus Scanning Implemented in July 2022
  - Implement enhanced enterprise virus scanning software at the Agency level prior to downstream FDA Center submission processing
  - Benefit: This enhances ESG security by adding another layer of protection prior to reaching the FDA intranet.

ESG Enhancements 2023

- *ESG Core Technology Refresh / Enhancements*

- Completed March 2023
  - Migrated ESG database, services and software to a GovCloud FedRAMP High Infrastructure
  - Implemented Center user functionality within the Account Portal
  - Benefits:
    - Supports FDA Technology Modernization Action Plan (TMAP) and Data Modernization Action Plan (DMAP) strategies
    - Reduces Data Centers footprint, provides a cost savings of operating maintenance for all centers, and aligns with FDA's mission of going green
    - Upload time between industry user environment to ESG server in AWS improved by 34% compared to ADC server (on-prem)
    - Makes use of modern cloud technology and enables scalability when the need arises
    - A more reliable environment in a 24x7x365 implementation

ESG Going Green

ESG is making changes which supports FDA's Going Green initiative

ESG Going Green Initiative

- Effective February 2023 FDA will now accept non-repudiation letters electronically.
- Industry is no longer required to send a hard copy of non-repudiation letters and doing so is optional.
- This will help to reduce the FDA and NARAs' carbon foot print and aligns with their going green initiative.

ESG Modernization Through PDUFA VII and BSUFA III Commitments

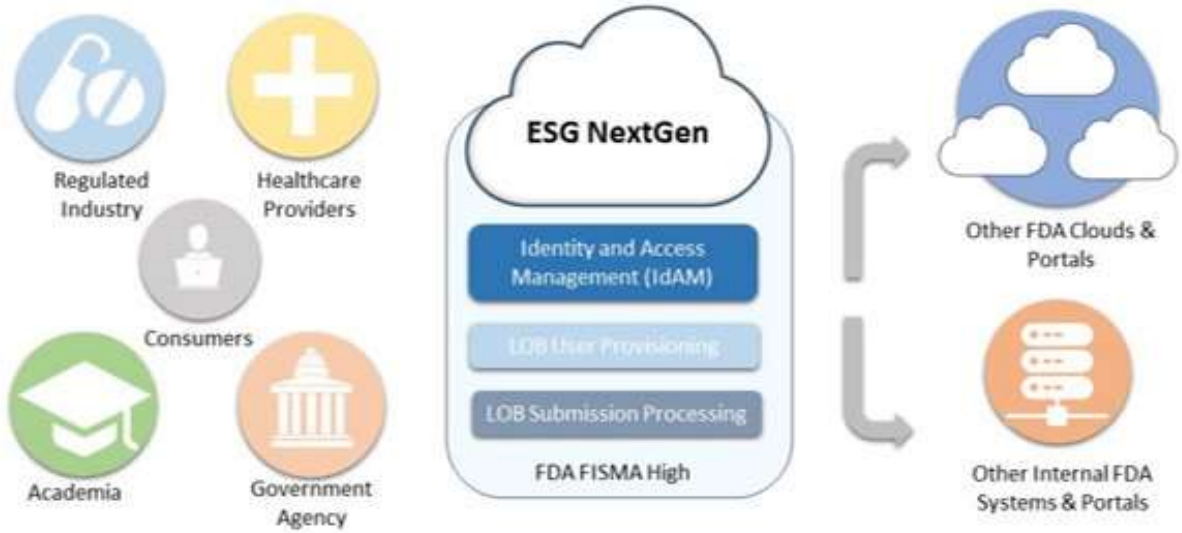
Learn how ESG is modernizing

ESG Modernization FY23 – FY25

- Continue modernization through Prescription Drug User Fee Act (PDUFA) VII and Biosimilar User Fee Act (BSUFA) III Commitments and other FDA Strategic Initiatives through the development of the ESG NextGen
- PDUFA VII - Monitor and Modernize ESG:
  - FDA will continue to ensure the usability and improvement of the ESG.
    a. Annually, FDA will provide on the ESG website historic and current metrics on ESG performance in relation to published targets, characterizations and volume of submissions, and standards adoption and conformance.
  - FDA will advance the ESG cloud-based modernization with an improved architecture that supports greatly expanding data submission bandwidth and storage, while continuing to ensure its stable operation.
    a. By the end of FY 2025, FDA will complete ESG transition to the cloud, including set-up and integration of an enterprise Identity and Access Management solution that will streamline applicant access to FDA resources.
    b. Annually, FDA will share progress against the implementation project plan.
    c. FDA will engage industry to provide feedback and/or participate in pilot testing in advance of implementing significant changes that impact industry's interaction with the enterprise-wide systems.

Vision For the Next Generation of ESG

To provide the FDA with a **trusted, secured cloud-based, and unified submission gateway** that is highly available, scalable, and accept a variety of electronic submissions for processing by line, or subject-specific, business processes.



ESG NextGen in Relation to FDA's Strategic Initiatives

FDA Strategic Initiatives:

Technology Modernization Action Plan (TMAP)

- Modernization of FDA's technical infrastructure;
- Enhancing FDA's capabilities to develop technology products to support its regulatory mission; and
- Communication and collaboration with stakeholders to drive technological progress that is interoperable across the system and delivers value to consumers and patients

Data Modernization Action Plan (DMAP)

- Identify and execute high value driver projects for individual centers and for the Agency;
- Develop consistent and repeatable data practices across the Agency; and
- Create and sustain a strong talent network combining internal strengths with key external partnerships

Enterprise Modernization Action Plan (EMAP)

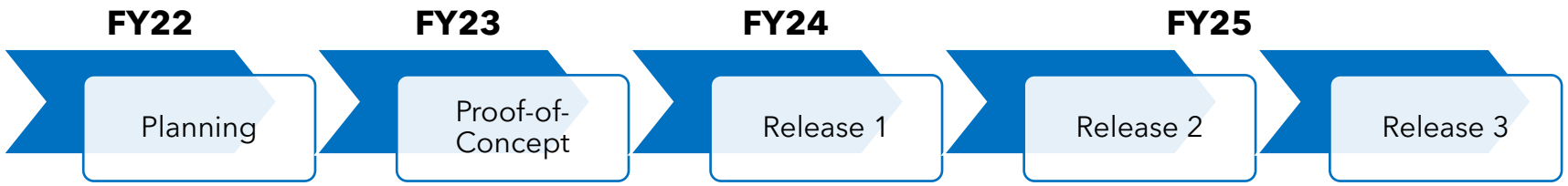
- Create the infrastructure to support change;
- Develop a common operational approach;
- Ensure strategic alignment

ESG NextGen Approach

- Product approach using personas
  - Industry Power User
  - Industry Submitter
  - ESG Admin
  - Center Admin
  - FDA Center User
- Complete technology refresh with latest cloud-based and best-of-breed software
- Examine current business processes and pain points to deliver a better user experience for external and internal users
- Collaborate with internal FDA stakeholders and industry to solicit feedback and validate functionality

ESG NextGen Business Process Improvements

ESG NextGen Targeted Milestones



Develop vision and planning

Develop proof-of-concept

- Unified Submission Portal
- Identity / Account Management
- User Interface (UI) / Application Programming Interface (API)
- Data Migration

- Enhanced Unified Submission Portal / Dashboard
- Self-service capability

- Large file size submission
- Chatbots
- Additional portal features

- Industry outreach and planning (quarterly basis)
- Develop testing strategy with industry and solicit testers
- Update ESG NextGen website with information, specification, user guides, Frequently Asked Questions (FAQs), progress, etc.
- Conduct testing with industry on each release before going live, incorporating lessons learned

Challenge Question #2

- The ESG NextGen Modernization will incorporate all of the following Business Process Improvements EXCEPT?

A. Improve Customer Experience

B. Improve File Transfer Process

C. Check Submissions For Spelling Errors

D. Improve User Management Process

Key Take Aways & Questions

Any questions?

Key Take Aways

- Current ESG has been the FDA central intake portal since 2005
- Since 2015, annual average increase of 17% in submission volume and data size
- Modernize ESG to accommodate a continued rate of growth well into the future
- Current ESG has met all PDUFA requirements to date
- The current ESG has served us well; however, as technologies and user requirements change, the FDA is assertively taking actions to assure ESG will meet future industry, technology, security, and public requirements.
- ESG NextGen will address pain points in the legacy ESG and will leverage technological advances to provide a modern and secure electronic submission gateway for industry and to provide critical information to the FDA

Questions

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Office of Information Management Technology (OIMT)

Office of Digital Transformation (ODT)

Office of the Commissioner (OC)

For More Information

- Web Site:
  - http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm

- Email:
  - ESGHelpDesk@fda.hhs.gov