FDA Electronic Submissions Gateway (ESG)

Transparency & Modernization

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Learning Objectives...

1. Describe what ESG is and how it is used today

2. Review how ESG collaborates and communicates with Industry

3. Illustrate how ESG has grown over the years, and

4. Outline plans for current ESG enhancements

5. ESG Next Gen future vision
ESG Today

External Submitters → FDA → FDA ESG Center Inboxes

WebTrader → AS2

Send Submissions

Receive Receipt / ACK

*HC submissions are forwarded to HC AS2 system
ESG Transparency and Collaboration

Per 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.
ESG Transparency and Collaboration (cont’d)

• 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
Per PDUFA: “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.”

- Submission Times / Business and Non-Business Hours
  Submission Times | FDA

- Monthly / Annual Metrics
  Submission Statistics | FDA
ESG Metrics (2015 – 2021)

Total submissions:

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<tr>
<td></td>
<td>3,100,970</td>
<td>3,895,669</td>
<td>4,055,342</td>
<td>4,841,844</td>
<td>5,428,492</td>
<td>5,728,006</td>
<td>7,258,031</td>
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Total transactions:

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<td>9,209,782</td>
<td>12,082,860</td>
<td>12,333,127</td>
<td>14,596,282</td>
<td>16,898,047</td>
<td>17,917,796</td>
<td>23,218,281</td>
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Average Annual Growth 2015-2021

- Submissions: 16%
- Acknowledgments: 17%
- Data: 25%
- Accounts: 16%
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
Three phases...

ESG *Continued* Enhancements 2021 – 2023
ESG Enhancements 2021 – 2023

Phase 1: Account Portal 1.0 and Submission Virus Scanning

Target Completion August 2022

- Deliver new front end portal - enhances user experience and automates the onboarding account management process; enables power user account administration
- Implement enhanced enterprise virus scanning software at the Agency level prior to downstream FDA Center submission processing
ESG Enhancements 2021 – 2023 (cont’d)

Phase 2: ESG Core Technology Refresh / Enhancements

Target Completion September 2022

- Migrate ESG core components to a GovCloud FedRAMP High Infrastructure
- Implement Account Portal 1.1 with enhanced Center user functionality
Phase 3: Enhanced ESG Architecture

Target Completion December 2023

• Explore GovCloud storage technologies as Center system repositories can accommodate
• Modernize the ESG submission receipt process with cloud-native technologies
ESG Modernization

What’s next???

Continue modernization through PDUFA VII Commitments and other FDA Strategic Initiatives (aka Next Generation ESG)
PDUFA VII:

• 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.

• 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.
FDA Strategic Initiatives:

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<th>Technology Modernization Action Plan (TMAP)</th>
<th>Data Modernization Action Plan (DMAP)</th>
<th>Enterprise Modernization Action Plan (EMAP)</th>
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<td>• Modernization of FDA’s technical infrastructure;</td>
<td>• Identify and execute high value driver projects for individual centers and for the Agency;</td>
<td>• Create the infrastructure to support change;</td>
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<td>• Enhancing FDA’s capabilities to develop technology products to support its regulatory mission; and</td>
<td>• Develop consistent and repeatable data practices across the Agency; and</td>
<td>• Develop a common operational approach;</td>
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<td>• Communication and collaboration with stakeholders to drive technological progress that is interoperable across the system and delivers value to consumers and patients</td>
<td>• Create and sustain a strong talent network combining internal strengths with key external partnerships</td>
<td>• Ensure strategic alignment</td>
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Next Generation ESG Vision

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.
NG ESG Business Process Improvements

Summary of the Objectives

Streamline Industry Account Onboarding Process
Streamline manual user onboarding process by using modern intelligent business process management platform and ICAM solutions

Improve Customer Experience
Reduce HelpDesk calls and improve customer experience by using CRM tool to provide updates on submission status and enable two-way communications between centers and users

Improve File Transfer Process
Increase file submission processing speed, support file resume transfer function, handle large file sizes, and reduce the complexity in generating the proper submission packages

Improve User Management Process
Consolidate users accounts and manual access management functions into a unified Enterprise Identity, Credential, and Access Management (ICAM) solution for end users

Support New Use Cases
Ensure future capabilities of ESG NG by incorporating new technologies that can support future use cases
Challenge Question #2

How many phases are included in the ESG’s 2021-2023 enhancement effort?

A. One
B. Two
C. Three
D. Four
ESG Transparency and Collaboration - Summary

- 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

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.
Questions?

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