U.S. FOOD & DRUG ADMINISTRATION

FDA Electronic Submissions Gateway (ESG)

Transparency & Modernization

Presented by:

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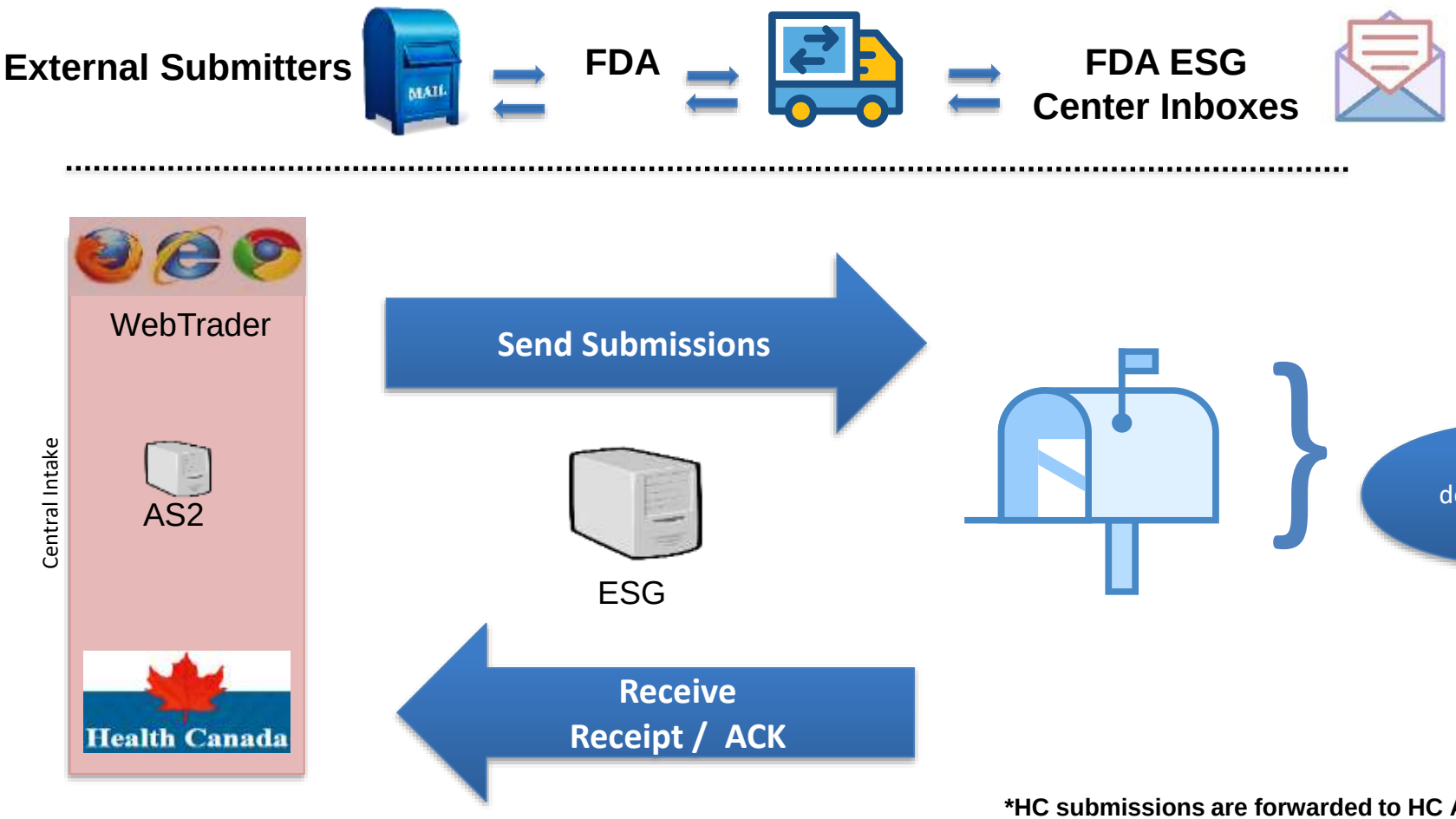
Learning Objectives…

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



*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

ESG Transparency and Collaboration (cont'd)

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)

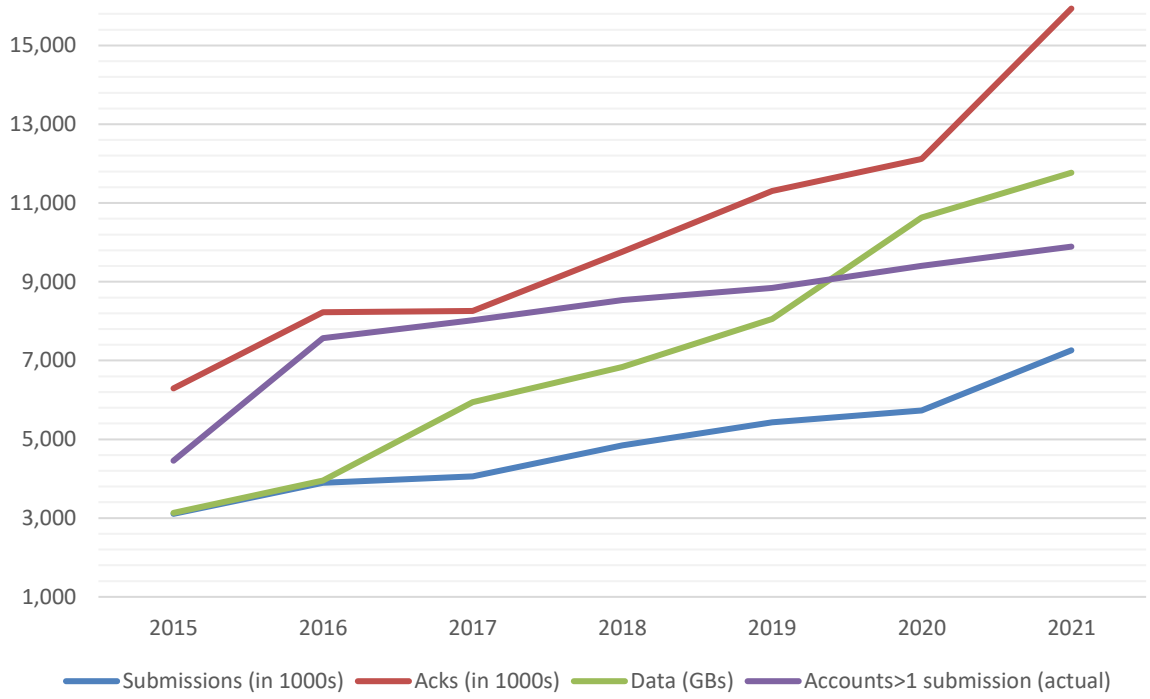
Total submissions:

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

Total transactions:

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

Average Annual Growth 2015-2021	
Submissions	16%
Acknowledgments	17%
Data	25%
Accounts	16%



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

Current ESG Enhancements

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

ESG Enhancements 2021 – 2023 (cont'd)

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*)

ESG Modernization (cont'd)

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.

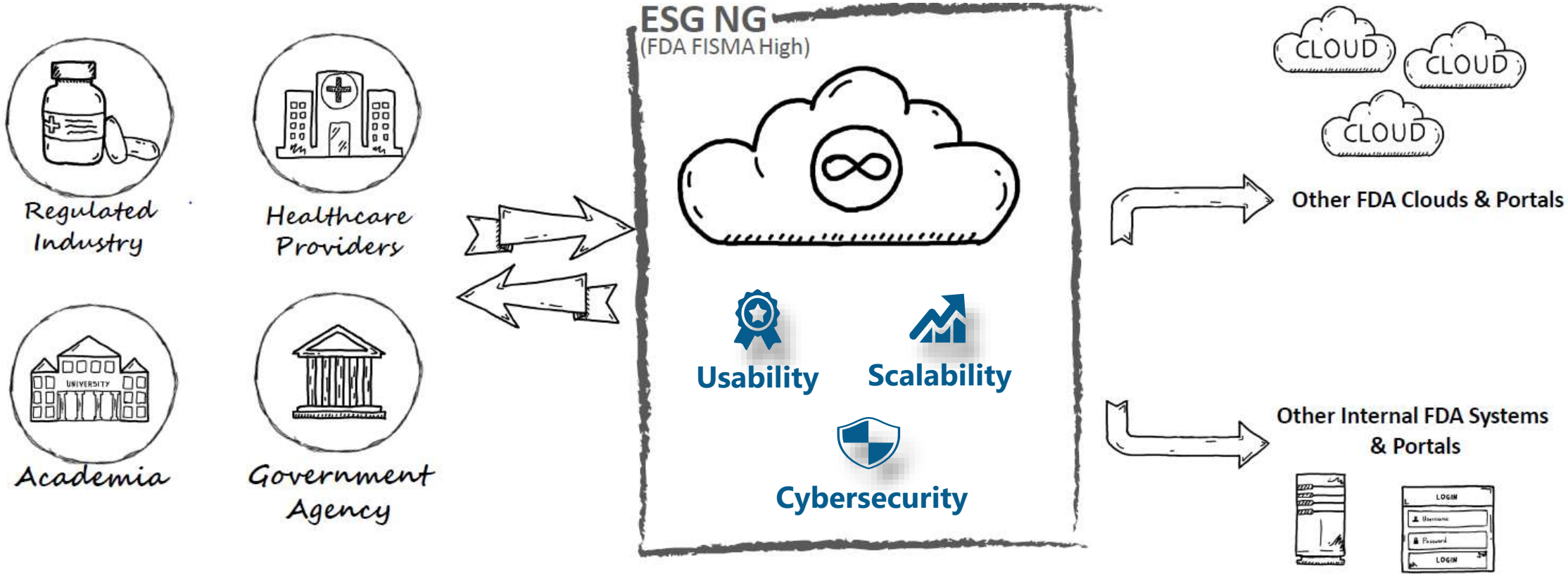
ESG Modernization (cont'd)

FDA Strategic Initiatives:

Technology Modernization Action Plan (TMAP)	Data Modernization Action Plan (DMAP)	Enterprise Modernization Action Plan (EMAP)
• 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	• 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	• Create the infrastructure to support change; • Develop a common operational approach; • Ensure strategic alignment

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

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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