



FDA Electronic Submission Gateway – Next Generation (NextGen)

SBIA Industry Presentation

May 30, 2024

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AGENDA

- ☐ What is ESG NexGen
- ☐ ESG NextGen Background & Vision
- ☐ Industry Engagement & Collaboration
- ☐ Demo
- ☐ Key Take Aways
- ☐ Questions & Answers

What is ESG NextGen?

Learn about
what ESG
NextGen is

What is the Electronic Submission Gateway Next Generation (ESG NextGen)

- The Food and Drug Administration (FDA) Electronic Submissions Gateway Next Generation (ESG NextGen) is the replacement of the current ESG. ESG NextGen is the Agency-wide solution for accepting electronic regulatory submissions. The FDA ESG NextGen enables the secure submission of premarket and postmarket regulatory information for review.
- The FDA ESG NextGen will be the central transmission point for sending information electronically to the FDA.

How Will ESG NextGen Submission Process Work – Unified Submission Portal (USP)

1. After the one-time registration, a user authenticates using Multi-Factor Authentication.
2. User uploads submission package within the Unified Submission Portal (USP) and submits to FDA.
3. ESG NextGen receives the submission and assigns a unique ID.
4. FDA ESG NextGen sends a Receipt to the submitter upon successful submission.
5. The submission is automatically transferred to the Center's Inbox.
6. A Center Acknowledgement is automatically generated and sent to the submitter via the FDA ESG NextGen.
7. The Center validates and processes the submission by accessing Center's Inbox.
8. Submission history and status is available within the USP.

FDA Centers/**International Partner** Receiving ESG **NextGen** Submissions

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



Background & Vision

Learn about the
background and
vision of ESG
NextGen

ESG NextGen Industry Commitments

FDA will advance the ESG NextGen cloud-based modernization with an improved architecture that supports greatly expanding data submission bandwidth and storage, while continuing to ensure its stable operation



End of FY25, FDA will complete ESG NextGen modernization in the cloud, including set-up and integration of an enterprise Identity and Access Management solution that will streamline applicant access to FDA resources.



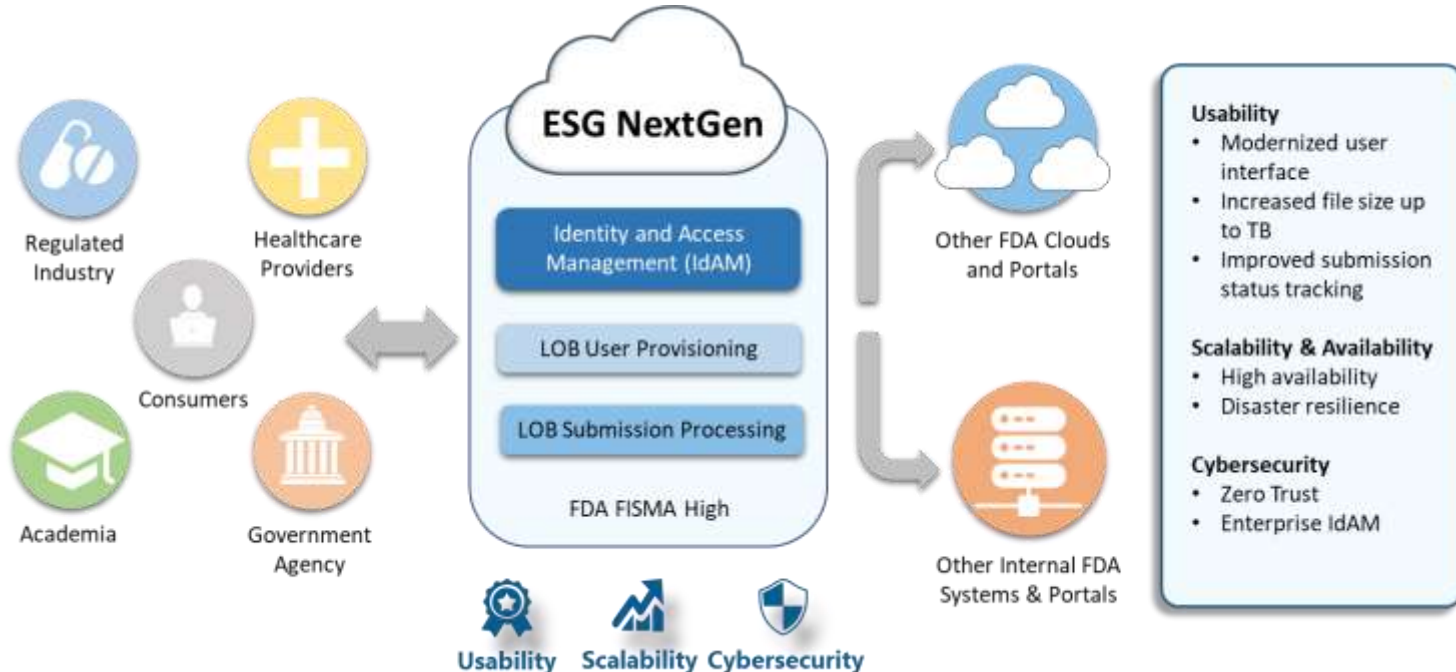
Annually, FDA will share progress against the implementation project plan.



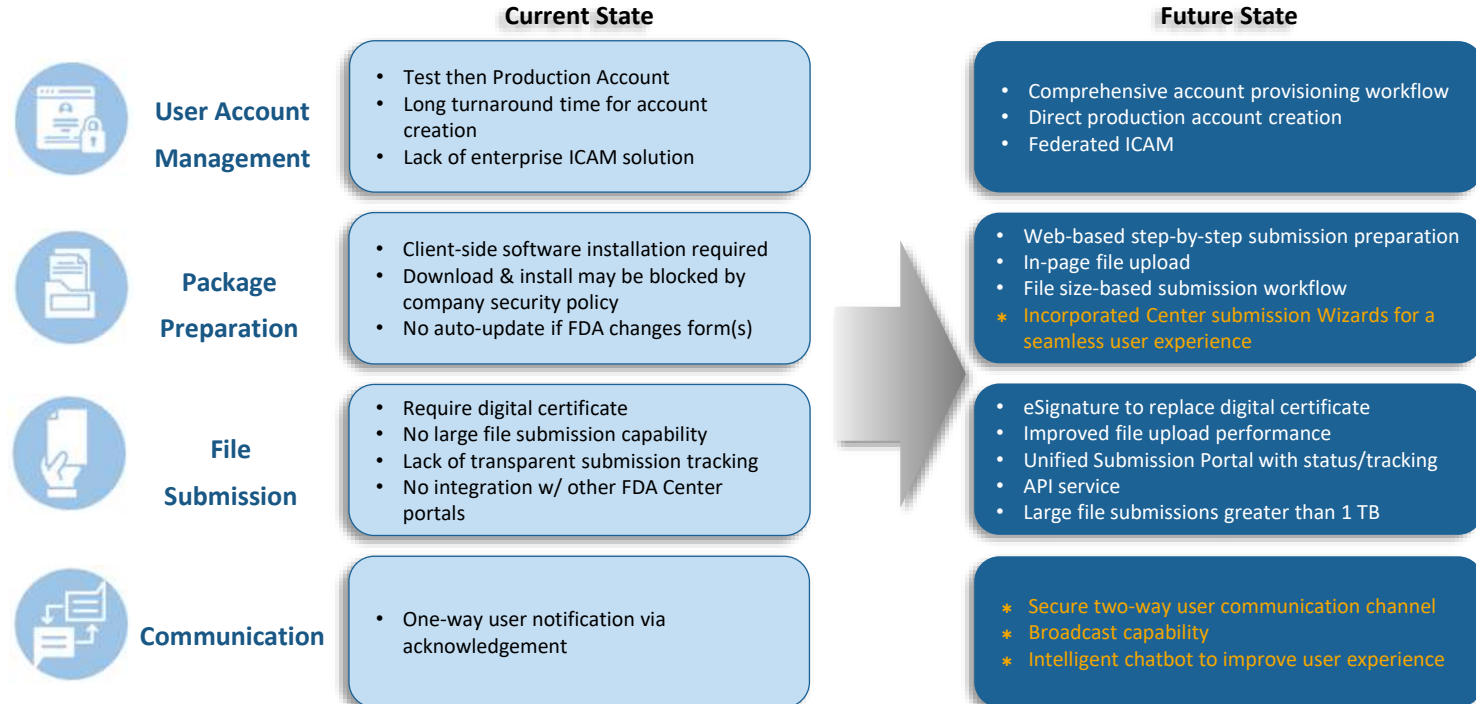
FDA will engage industry to provide feedback and/or participate in pilot testing in advance of implementing significant changes that impact industry's interaction with the enterprise-wide systems.

ESG NextGen Vision

To provide the FDA with a **trusted, secured, cloud-based**, and **Unified Submission Portal** that is highly available and scalable, and that can accept a variety of electronic submissions for processing by line-of-business (LOB) processes.



Improving User Experiences



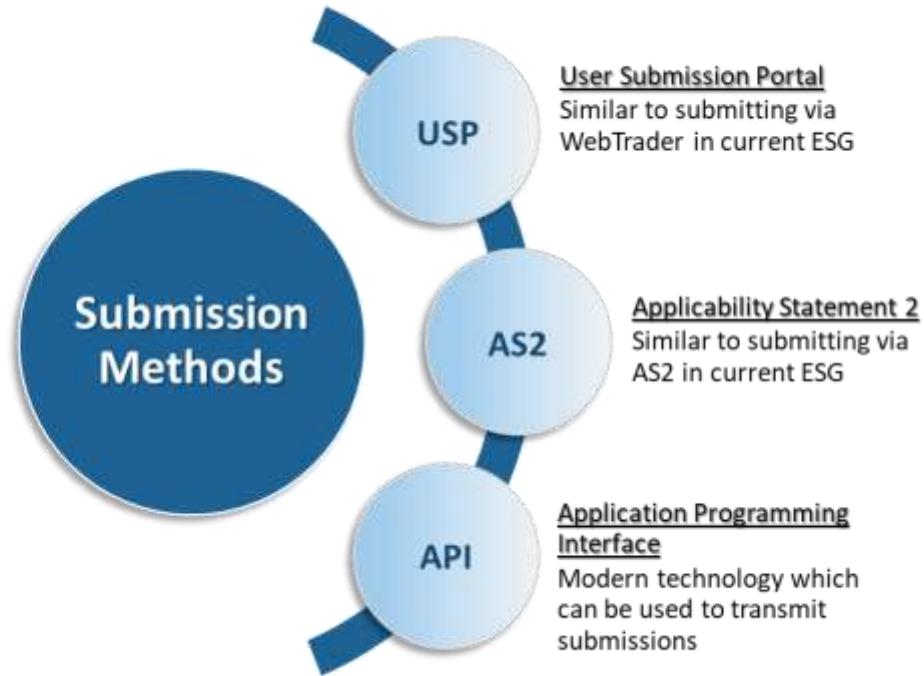
★ Outside the scope of PDUFA/BsUFA requirements

Challenge Question #1:

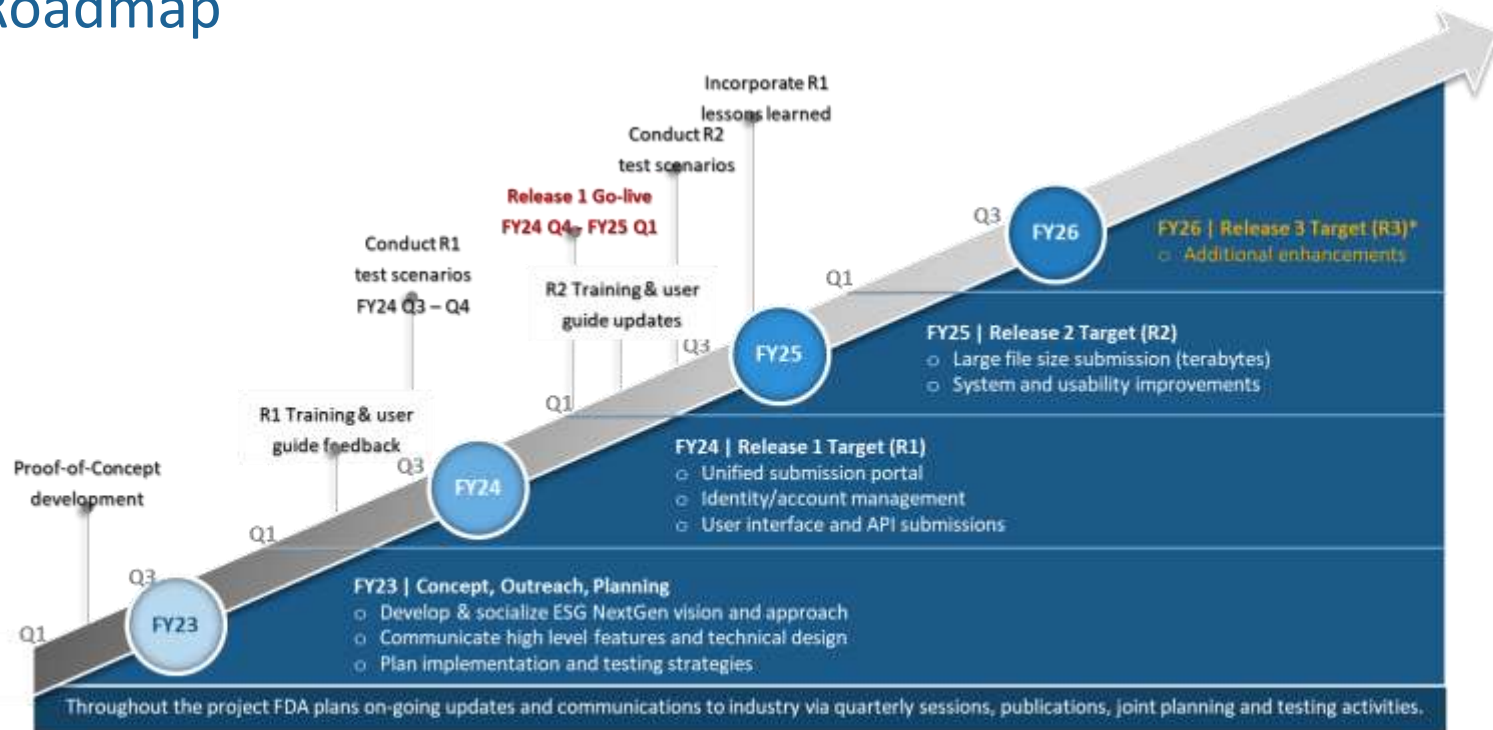
In what way is ESG NextGen Improving Customer Experience?

- A: Modern User Interface
- B: Improved Usability
- C: Provide submission status transparency
- D: All of the above

ESG NextGen Industry Submission Methods



Roadmap



Future enhancements communicated as part of the ESG NextGen Vision, but are not currently funded and outside the scope of PDUFA commitments

Challenge Question #2:

How Many Different Submission Methods are available in ESG NextGen?

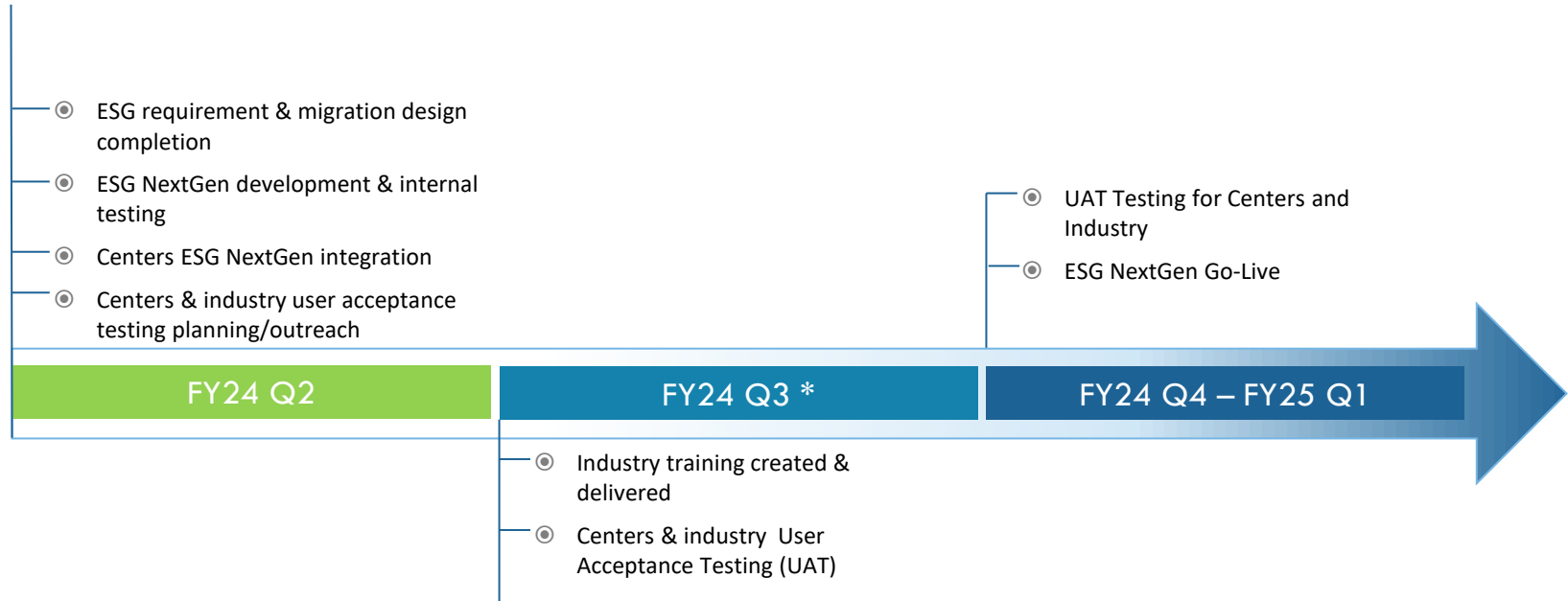
A: 5

B: 3

C: 2

D: 4

Release I High level Timeline



Legend: ■ Completed * In Progress

Challenge Question #3:

When is the planned go live for ESG NextGen?

A: 2026

B: FY25 Q3

C: FY24 Q4 – FY25 Q1

D: None of the above

ESG NextGen Industry Testing Phases

Phase	What To Do
Pre-UAT Q2 – Q3	<ul style="list-style-type: none"> • Preparation for UAT <ul style="list-style-type: none"> ◦ Select Industry Testers Participate in training ◦ Review UAT training materials
Wave 1 Q3 – Q4	<ul style="list-style-type: none"> • Test submissions via Unified Submission Portal (USP) • Test new user registration & management • Test submissions via Restful APIs
Wave 2 Q4	<ul style="list-style-type: none"> • Test submission via AS2 • Test existing ESG user accounts migration • Re-test improvements from UAT feedback in Wave 1 testing

Industry Engagement & Collaboration

Learn about how
ESG NextGen
Project
Collaborates
with Industry

ESG NextGen Industry Impact

Area	ESG	ESG NextGen	Change for Industry	Risk Mitigation Plan
User Interface	WebTrader	Unified Submission Portal	Modernized UI to: <ul style="list-style-type: none"> • Upload files • Manage Users • Access Submission History 	<ul style="list-style-type: none"> • User accounts migration • User acceptance testing • Detailed training sessions • User guide documentation
Electronic Submissions	AS2	AS2	Minimal Changes: <ul style="list-style-type: none"> • DNS & Certs will remain the same • Callback password will be resubmitted to FDA • IP address will change to point to ESG NextGen 	<ul style="list-style-type: none"> • AS2 accounts migration • User acceptance testing • Training sessions • User guide documentation
Electronic Submissions	-----	API	<ul style="list-style-type: none"> • API will be available for use • Industry can plan for future development • Large file submissions up to 1TB 	<ul style="list-style-type: none"> • User acceptance testing • Training sessions • User guide documentation
Customer Support	ESG Helpdesk solution	ESG Helpdesk solution	No Change	-----

Challenge Question #5:

How many UAT waves are there?

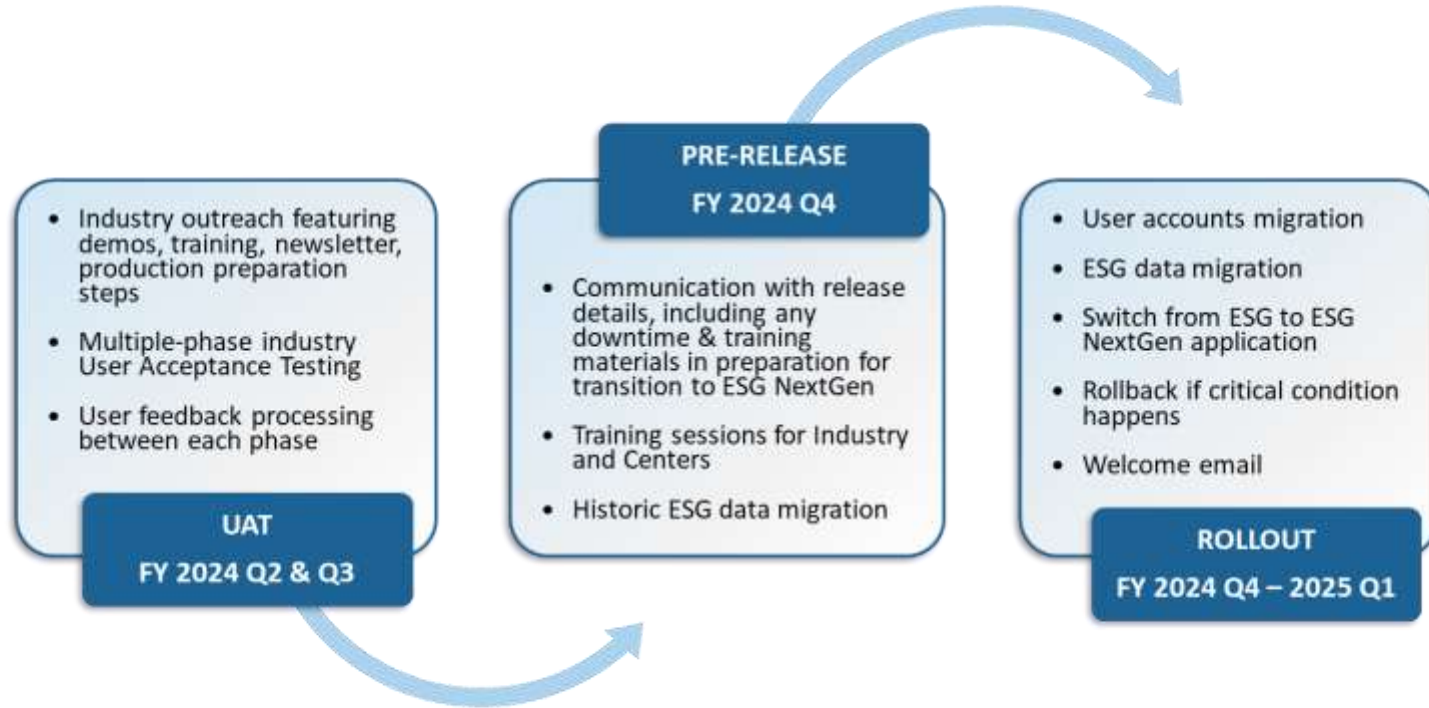
A: 3

B: none

C: 2

D: 1

ESG NextGen Tentative Release Rollout Plan



FDA Engagement

- Go to the ESG NextGen Website for up-to-date information <https://www.fda.gov/industry/esg-next-generation>
- Please email esgngsupport@fda.hhs.gov with questions; initial response SLA is two business days



ESG NextGen Centers, FDA Stakeholders, And Industry Outreach Statistics

Center Engagements

37

Participants Questions
520 150

Industry Engagements

12

Participants Questions
2,125 501

UAT Volunteers



175

Center Communication



100 Recipients

Industry Communication



12,000 Recipients

Challenge Question #4:

Will ESG NextGen replace the current ESG?

A: Yes, Legacy ESG will be retired when ESG NextGen goes live.

B: No, only certain submission types will use ESG NextGen.

C: It will be industry's choice to use ESG NextGen.

D: Using ESG NextGen will depend on the Center receiving the submission.

Demo

Get a sneak peak
of the ESG Next
Unified
Submission
Portal

Signed in as Sean Mitt

PROFILE

SETTINGS

SIGN OUT

Unified Submission Portal

Action Center

Thank you for registering for an ESG NG account. To complete the process, click the "Complete Registration" button below and follow the instructions. Once your information has been submitted, your account will be approved or rejected, pending review. You will be emailed in the case that your account has been reviewed, or if we have any additional questions.



Complete Registration

Key take Aways & Questions

Any Questions?

Key Take Aways

- ESG NextGen is the modernization of the current Electronic Submission Gateway (ESG).
- The modernization of ESG has been a collaborative effort between FDA Information Technology, the FDA Centers, **International Partner** and Industry .
- ESG NextGen will be a modern cloud-based solution which will improve the user experience, increase usability and scalability, and implement and identify and access management solution.
- The planned go-live for ESG NextGen is FY24 Q4 to FY25 Q1.
- ESG NextGen will fulfill Industry commitments, align with the FDA strategic direction by creating enterprise services, and will further the vision of “One FDA”.

Questions

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Office of Information Management Technology (OIMT)

Office of Digital Transformation (ODT)

Office of the Commissioner (OC)