

**U.S. Food and Drug Administration (FDA)**



**Electronic Submission Gateway (ESG) NextGen  
User Acceptance Test Guide for  
Industry Users**

**Unified Submission Portal  
Version 3.0  
October 28, 2024**

# Contents

- 1 Purpose ..... 2**
- 2 ESG NextGen Introduction ..... 2**
- 3 UAT Introduction ..... 3**
  - 1.1 UAT Schedule ..... 3
    - 1.1.1 Wave 1: July 2024 – August 2024..... 3
    - 1.1.2 Wave 2: September 2024 – October 2024 ..... 4
    - 1.1.3 Wave 3: October 2024 – October 2024..... 4
  - 1.2 UAT Training and Support ..... 4
  - 1.3 UAT Guide Structure ..... 4
- 4 Prerequisite: FileCatalyst Installation..... 5**
  - 1.1 System Requirements ..... 5
  - 1.2 FileCatalyst TransferAgent Installation..... 5
- 5 ESG NextGen Functional Modules..... 5**
  - 1.1 User Registration ..... 6
    - 1.1.1 Entities in ESG NextGen ..... 6
    - 1.1.2 Letters ..... 6
    - 1.1.3 Migrated User Registration ..... 7
    - 1.1.4 Testing Functions in User Registration ..... 7
    - 1.1.5 Tips for User Registration ..... 7
  - 1.2 User Management..... 7
    - 1.2.1 Roles and Permissions ..... 7
    - 1.2.2 Tester Functions in User Management ..... 8
  - 1.3 File Submission..... 9
    - 1.3.1 Testing File Submission Functions..... 10
  - 1.4 Submission History ..... 10
    - 1.4.1 Testing Submission History Functions ..... 11
    - 1.4.2 Migrated Data..... 11
- Appendix 1. Troubleshooting Common Issues ..... 11**
- Appendix 2. Wave 3 Tips for UAT ..... 12**
- Appendix 3. Glossary of Key Terms ..... 14**
- Appendix 4. Acronyms ..... 16**

# Tables

- Table 1. Role Functionality to Be Tested ..... 9**
- Table 2. ESG NextGen Acknowledgement Types..... 10**

# 1 Purpose

This User Acceptance Testing (UAT) guide is a supporting document for testers participating in the UAT of the Food and Drug Administration (FDA) Electronic Submission Gateway Next Generation (ESG NextGen) Unified Submission Portal (USP). It introduces ESG NextGen and describes key ESG NextGen terms and functional modules of the USP. It also outlines functions to be tested in each functional module. This document, together with “UAT Testing Scripts for Industry Users, Unified Submission Portal,” prepares and guides testers to conduct UAT for ESG NextGen.

## 2 ESG NextGen Introduction

ESG NextGen addresses some major pain points of the legacy ESG in user management, package preparation, and file submission and introduces new business processes and technologies to streamline the submission process, enhance user experience and improve security, as described below.

**User Account Management:** ESG NextGen integrates with FDA’s state-of-the-art enterprise security features and introduces comprehensive account provisioning workflow, multi-factor authentication and advanced access management capabilities. In addition, instead of provisioning user accounts in a test environment and then migrating them to the legacy ESG production environment, ESG NextGen provisions user accounts directly in the production environment, significantly reducing the account provisioning time.

**Submission Package Preparation:** ESG NextGen modernizes the user experience (UX) and replaces the legacy ESG User Interface (UI) with the new USP, which provides step-by-step guidance to prepare a submission package.

### **File Submission Improvements:**

- Legacy ESG requires users to submit a digital certificate to electronically sign (e-sign) the submission package. For small businesses with minimal or no Information Technology (IT) support, obtaining and submitting a digital certificate can be difficult. In ESG NextGen, the digital certificate is replaced by the widely adopted e-Signature to sign a submission package.
- ESG NextGen uses a modern browser plug-in to enhance the file upload experience. The plug-in provides multi-thread capability to parallelize and accelerate file upload performance. In addition, it ensures file delivery by automatically resuming the file upload after an interruption, as well as providing checksum verification to guarantee file integrity.
- By leveraging modern, cloud-based network technologies, ESG NextGen dramatically increases the file size upload capacity. In Release 1, ESG NextGen

can take up to a 1TB file submission. Further increases in file size will be developed in future ESG NextGen releases.

- ESG NextGen provides web service Application Programming Interfaces (APIs) to submit files and check submission status. The APIs enable companies to potentially integrate file submission with their IT systems to achieve submission automation.
- ESG NextGen enables users to track the status of their submissions via the USP, APIs and emails and to view details on FDA Acknowledgements.

**File Submission Options:** ESG NextGen provides three interfaces for industry to submit files to the FDA:

- **USP:** The USP was developed to address the business process integration, UX, self-service, and communication gaps of the legacy ESG. USP seamlessly integrates user registration, user account management, package preparation and submission, status tracking, reports and dashboards in a web-based UI with a modern look and feel resulting in an improved UX.
- **APIs:** ESG NextGen provides new web services APIs to submit files, check submission status and query other information. Companies can integrate these APIs with their systems to achieve submission and other business workflow automation.
- **Application Statement 2 (AS2):** ESG NextGen will continue to support AS2, an electronic data interchange protocol used in the legacy ESG to submit files to FDA.

## 3 UAT Introduction

FDA is excited to engage with the industry for ESG NextGen UAT. This testing is a critical phase in which participants are invited to test the end-to-end functionalities of ESG NextGen and provide feedback on system functions, performance, their UX, and anything else on which they care to comment.

### 3.1 UAT Schedule

UAT will unfold in two waves, each targeting different ESG NextGen functionalities. This manual outlines the testing schedule and functionalities for each wave and guides participants through the process.

#### 3.1.1 Wave 1: July 2024 – August 2024

- Test new user registration and user management features
- Test submissions via the USP
- Test submissions via APIs

In Wave 1, all users will need to set up new accounts in ESG NextGen to test the user registration process. For details on how to register new users, see section 5.1 User Registration.

### 3.1.2 Wave 2: September 2024 – October 2024

- Test submissions via AS2
- Test legacy ESG user accounts migration
- Re-test improvements from UAT feedback in Wave 1

In Wave 2, user accounts will be migrated from the legacy ESG to ESG NextGen. Testers who have accounts in the legacy ESG will receive an email notification with the account registration steps required to activate their accounts in ESG NextGen.

### 3.1.3 Wave 3: October 2024 – November 2024

- Submissions via AS2, USP and API
- Re-test improvements from UAT feedback in Wave 2
- Batch Upload
- Data Migration

In Wave 3, user accounts were migrated from the legacy ESG to ESG NextGen while their authentication username and password from Wave 2 will remain active.

## 3.2 UAT Training and Support

**Frequent Asked Questions:** UAT participants can check [ESG NextGen Frequently Asked Questions | FDA](#) for all FAQs related to ESG NextGen.

**UAT Training:** Demo videos, previous industry demo recordings, the UAT guide and UAT Testing Scripts are available at the [ESG NextGen UAT Landing Page](#). The ESG NextGen team plans to hold UAT kickoff and training sessions before UAT starts.

**UAT Drop-in Sessions:** During UAT phases, the ESG NextGen team plans to host weekly sessions to demonstrate ESG NextGen functionality, answer questions, and collect feedback from testers. A detailed schedule of the sessions will be announced when UAT starts.

**Technical Support:** UAT participants can email with questions or to request technical support. When requesting technical support, please include in the email a detailed description of the issue, any error messages, and screenshots, if applicable, to assist the ESG NextGen Support Team in diagnosing the issue. Please use the [ESG NextGen Software Issue Report Form](#) to document issues whenever possible.

## 3.3 UAT Guide Structure

This UAT Guide for Industry is one of a few available UAT Guides. This guide is accompanied by a Test Case document. The guides provide general information, and the test cases provide step by step instructions for testers. In addition, there is a UAT

Guide for API. Test cases for API are embedded in the Test Case document for the Industry.

The scope of this guide and related User Acceptance Test Cases for Industry is that of the Power User and Submitter user experience.

## 4 Prerequisite: FileCatalyst Installation

To engage with the submission functionalities of ESG NextGen within the USP, FileCatalyst must be installed. The ESG NextGen USP UI will walk users through the installation process as part of the workflow of the first submission. UAT participants may have to reach out to their technical support team to obtain permission to download FileCatalyst.

FileCatalyst is a market leading Managed File Transfer (MFT) software product that facilitates fast and secure file transfers. ESG NextGen uses FileCatalyst TransferAgent, a web browser plug-in, for file submission. For detailed information on the product, visit [FileCatalyst | Fortra](#).

### 4.1 System Requirements

To install FileCatalyst TransferAgent in a computer, these minimum system requirements must be met:

- Dual Core processor, 2GB RAM, 80MB free disk space
- Windows 10, macOS 10.14 or higher, 64-bit
- Recommended browsers: Chrome, Firefox, Edge
- Broadband Internet connection and network connectivity to the FileCatalyst Direct Server

### 4.2 FileCatalyst TransferAgent Installation

Below are links which can be provided to company technical support teams regarding the installation of the FileCatalyst TransferAgent.

**Windows:** [FileCatalyst TransferAgent Windows Installation Guide](#)

**Mac:** [FileCatalyst TransferAgent Mac OSX Installation Guide](#)

**Linux:** [FileCatalyst TransferAgent Linux Installation Guide](#)

## 5 ESG NextGen Functional Modules

The following sections describe each of the ESG NextGen functional module.

## 5.1 User Registration

ESG NextGen introduces a streamlined and user-friendly approach to register new users, set up profiles, and manage roles and permissions. This section is dedicated to ensuring that all testers are equipped with the knowledge and tools needed to navigate the registration process.

ESG NextGen begins with the user registration process. This first step ensures users are properly identified within the system, enabling secure and personalized access to its features. This Guide provides information on creating an account from entering information through selecting the appropriate user type/ role in the submission process. Special attention is given to the multi-factor authentication setup, ensuring each user's access is protected against unauthorized use.

### 5.1.1 Entities in ESG NextGen

There are two entities in ESG NextGen.

- **Company:** A company is a United States (U.S.) or international business entity that uses ESG NextGen to file regulatory or voluntary submissions to FDA.
- **Agency:** An agency is a special type of company. It can be a Contract Research Organization (CRO), a U.S. agent company, or a consulting company. The agency is contracted by an authorizing/sponsoring company to file a submission to FDA on its behalf. Users as Agents must obtain and upload their authorization letter from the authorizing/sponsoring company before they can file a submission for that company.

### 5.1.2 Letters

**Authorization Letter:** An authorization letter is a document issued by a company that grants an agent permission to submit to the FDA on the company's behalf.

The FDA has revised regulatory guidance to allow for the electronic delivery of documents. Instead of mailing a paper copy, users can submit these documents electronically, enhancing efficiency and reducing paperwork.

**Non-Repudiation Letter (NRL):** An NRL is a formal document submitted to the FDA that certifies electronic signatures from a company's employees, agents, and/or representatives are legally binding (i.e., equivalent to traditional handwritten signatures). This letter is crucial for registering as a transaction partner with the FDA.

An NRL can cover all employees, contractors, agents working for the company, or only cover individuals whose names are listed in the NRL. The NRL can be uploaded, or it can be created electronically in ESG NextGen and approved using e-signature.

When setting up a company in ESG NextGen, a Power User can upload an NRL that either covers every associate (company-wide) or an NRL to cover only themselves. When setting up a new user account:

- If the company the user is associated with has a company-wide NRL, then the user does not need to upload an NRL.

- If a company-wide NRL is not present, a user must upload an NRL covering themselves before they will be granted access to the functions to file a submission in ESG NextGen.

### 5.1.3 Migrated User Registration

UAT participants with an active legacy ESG WebTrader account will have their user information migrated to ESG NextGen.

These participants will receive an email from [FDA-SSO-Identity-Services@fda.hhs.gov](mailto:FDA-SSO-Identity-Services@fda.hhs.gov) with the subject line 'Your account has been created'. Please note, ESG NextGen will NOT be referenced in this email.

The email will contain your username and a generated temporary password.

Participants who receive this email will need to access the Industry UAT Landing Page to access ESG NextGen Log In. At log in, enter the username and temporary password provided in the email and walk through the steps to update your authentication information. You will then be able to login to ESG NextGen and will be taken to a 'Welcome' page to confirm your details.

### 5.1.4 Testing Functions in User Registration

- Register for the unified submission portal
- Create a company (if they are the first user of the company)
- Search for their company and select the type of NRL
- Upload their own NRL letter or have the system digitally create one
- Provide their company logo, signature, and title for the creation of a NRL
- Agent Only: Review and upload authorization letters for their agency

### 5.1.5 Tips for User Registration

**Use the Right Email.** Please make sure to enter a valid company email in the user registration process because ESG NextGen employs two-factor authentication. ESG NextGen sends a One-Time Passcode (OTP) to the user's email after their correct email and password are entered. The user needs to enter the correct OTP to login. Please make sure to enter a valid company email in the user registration process.

## 5.2 User Management

This section describes user management functions in ESG NextGen.

### 5.2.1 Roles and Permissions

Use of ESG NextGen features is dependent on the roles, and related permissions, designated within the system. The roles define what actions a user can perform, from

creating submissions to managing other users' access. Permissions are designed to ensure users have the access they need to perform their jobs efficiently while upholding the principle of least privilege to enhance system security.

There are two essential roles in ESG NextGen for industry users.

1. **Power Users:** Users with this role have privileges to create and update company information and approve/deny user requests within the company. They also have full access to all the submissions of the company. Specifically, Power Users can perform the following tasks:

- Edit company information
- View a company's NRLs and authorization letters
- Add a NRL
- Agent Only: Add authorization letters
- Make decisions to approve or reject pending users, providing reasons for rejections
- Review and change user roles
- Deactivate or reactivate a user
- Manage their own details in the "My Information" tab
- Request changes to their own role
- View Invited Users (for migrated companies/users)
- Create submissions for their company
- View details of all company submissions
- Obtain the API key and secret to be used for API calls

The first user who registers the company will automatically be assigned as the Power User of the company upon approval from the ESG NextGen Administrator. A Power User can promote other users from the company to the Power User role. ESG NextGen requires a minimum of one Power User per company but advises that each company should have at least two Power Users. There is no limit on the number of Power Users a company may have.

Migrated users with a legacy ESG role of Power User or Power User+ will be migrated to ESG NextGen as a Power User.

2. **Submitters:** Users with the submitter role have limited privileges compared to a Power User. Submitters can:

- Create submissions for their company
- View submissions they created/uploaded
- Request a role change

Migrated users with a legacy ESG role of Submitter/WebTrader User will be migrated to ESG NextGen as a Submitter.

## 5.2.2 Tester Functions in User Management

Table 1 below outlines, by role, the functions that should be tested in the user management module.

**Table 1. Role Functionality to Be Tested**

Role	My Information	Reviewed Users	Pending Users	Invited Users
Power User	<ul style="list-style-type: none"> <li>• View user and company information, NRLs, Authorization Letters</li> <li>• Request a role change</li> <li>• Add a new NRL if conditions are met</li> </ul>	<ul style="list-style-type: none"> <li>• View/search reviewed users</li> <li>• Deactivate/activate users</li> <li>• Change roles</li> <li>• Filters and grid columns for active/inactive status</li> <li>• Role</li> </ul>	<ul style="list-style-type: none"> <li>• View/search pending users</li> <li>• Filters and grid columns available</li> <li>• Dates submitted</li> </ul>	<ul style="list-style-type: none"> <li>• View/search all imported invited users</li> <li>• Filters and grid columns available</li> </ul>
Submitter	<ul style="list-style-type: none"> <li>• View user and company information</li> <li>• Request a role change</li> </ul>	Not allowed	Not allowed	Not allowed

Note: When a user requests a role change, they retain their current privileges and permissions, until a Power User reviews and approves their role change request.

### 5.3 File Submission

The submission process in ESG NextGen is designed to facilitate efficient and secure regulatory submissions. This section provides the essential steps, from preparing a submission package to monitoring its status.

**Preparation:** Users start by gathering the submission files and making sure they meet the FDA's submission standards. Users can still utilize eSubmitter ([FDA eSubmitter | FDA](#)) to package the submission files.

**Submission:** Follow the workflow presented in the USP to upload the submission files, enter information related to the submission, e-sign the submission and submit.

**Monitoring Submissions:** Once submitted, ESG NextGen provides real-time tracking and acknowledgement status to keep users informed of the progress of their submission.

In ESG NextGen, an "acknowledgment" (ACK) refers to the response sent by ESG NextGen after upload of a submission. The acknowledgement is sent by email to the submitter.

Table 2 lists the types of acknowledgements a submitter should expect to receive from ESG NextGen.

**Table 2. ESG NextGen Acknowledgement Types**

Acknowledgement	Reason for Sending
ACK1	<ul style="list-style-type: none"> <li>• A virus scan fails (using the USP, an API, or AS2)</li> <li>• Files have not been uploaded within 24 hours and the number of expected files received and the number of total files received are not the same (using the USP or an API)</li> <li>• All files have landed in ESG NextGen successfully</li> </ul>
ACK2	Submission is received by the Center
ACK3	Center's approval/rejection of the files submitted
ACK4	Utilized by CVM for eSubmitter submissions as a follow-up acknowledgement after an ACK3 was sent

### 5.3.1 Testing File Submission Functions

- Agent Only: Select the company for submission
- Provide package details such as Center, type, name, and additional notes
- Utilize e-signature functionality to acknowledge the completion of the package
- Receive confirmation of a submission and acknowledgment emails
- View acknowledgments in the user's inbox and through the USP

## 5.4 Submission History

Using ESG NextGen search capabilities, users can gain access to their submission history to maintain a comprehensive understanding of their activities. This module describes the functions ESG NextGen offers for exploring submission historical data using powerful tools to search, review, and analyze past submissions.

**Search with Single Return:** Users can use the Core ID (Identification), the unique identifier for a submission assigned by ESG NextGen, to conduct a search. The Core ID search returns details of a submission including the Center, submission type, file count, status, acknowledgement(s) details, and timestamps.

**Search with Multiple Returns:** Users can find the details for submission name, Center, submission type, and submission status, associated with multiple Core IDs. ESG NextGen can return multiple results as a list from which users can select any listed item to view submission details.

**Export Submission History to Excel:** ESG NextGen provides the ability to export submission history into Excel. This functionality supports users who require further data manipulation, a different reporting format, or to share report data outside the ESG NextGen environment.

## 5.4.1 Testing Submission History Functions

- Search by one or more Core IDs, Center, Submission Type, Submission Status, , and/or Date Range
- Review Core ID details including an ACK summary and status history

## 5.4.2 Migrated Data

ESG NextGen will be migrating the last 12 months of data from legacy ESG to ESG NextGen. Submission History can be utilized to validate historical submissions were migrated correctly.

# Appendix 1. Troubleshooting Common Issues

During the UAT phase, users may encounter a number of common issues as described in the Questions & Answers below. Users can also always reach out to the ESG NextGen Support Team for assistance by sending an email to [ESGNGSupport@fda.hhs.gov](mailto:ESGNGSupport@fda.hhs.gov).

- **Unable to log in or access the ESG NextGen portal?**
    - Ensure you are using the [correct URL](#) and credentials.
    - Check for any email instructions regarding one-time passcode (OTP) authentication.
  - **Error messages when submitting documents or data?**
    - Verify all required fields are entered correctly.
    - Verify your submission does not exceed the maximum file size limit of 1 TB.
    - Ensure the format of the files is supported by ESG NextGen.
    - If using API submissions, check for syntax errors in your request and reference the [API guide](#).
  - **Incorrect or missing data in the Dashboard?**
    - Refresh the Dashboard page.
    - If the issue persists, log out and log back in to reset the session.
    - Ensure your user role has the necessary permissions to view the data in question. For more information, see [Roles and Permissions](#).
  - **Issues installing or using FileCatalyst software for file transfers?**
    - Confirm your system meets the minimum System Requirements for FileCatalyst. For more information, see [System Requirements](#).
    - Follow the installation guide carefully, ensuring any required network and firewall configurations are in place. Contact your IT Support if the issue continues.
  - **Difficulties registering new users or managing user roles?**
-

- For role management issues, ensure the person attempting the change has the designated Power User role.
- Double-check the user information for accuracy before submitting.
- **Features not working as expected or encountering unspecified errors?**
  - Refresh your browser.
  - Clear your browser cache.
  - If the issue persists, send an email to the ESG NextGen support team at [ESGNGSupport@fda.hhs.gov](mailto:ESGNGSupport@fda.hhs.gov) and include the following information:
    - The steps taken leading up to the problem.
    - Information about, or a screenshot of, any error message(s) received.
    - If possible, screenshots about the problem or a recording of the issue.

## Appendix 2. Wave 3 Tips for UAT

As we close UAT with a final wave, please see this list of tips to ensure a smooth testing.

- **Batch Upload Enhancements in ESG NextGen**
  - In ESG NextGen, individual files in a batch upload now receive their own Core ID, to be consistent with legacy WebTrader process.
  - **Examples - Core ID Assignment for Batch Uploads:**
    - Uploading 300 individual file results in 300 Core IDs.
    - Uploading a single ZIP file with 5 files inside generates one Core ID, reflecting a count of 1 file.
    - Two separate ZIP files each containing 5 files generates two separate Core IDs, with a file count of 1 each.
    - Uploading a folder with 100 files results in one Core ID for the folder with a count of 100 files.
- **ACK Messages for AS2 Submissions**
  - Standardized Message ID in ACKs:
    - ESG NextGen has standardized its ACK message format for AS2 submissions to match legacy ESG.
    - Message ID will now be included in all AS2 ACK messages, ensuring consistency with prior processes, and making it easier for users to track submissions across systems.



## Appendix 3. Glossary of Key Terms

Below is a list of terms used in the ESG NextGen system or documentation.

Term	Definition
Acknowledgement (ACK)	A response sent by ESG NextGen indicating the status of a submission. For information about the four types of acknowledgements in ESG NextGen, refer to <a href="#">Table 2. ESG NextGen Acknowledgement Types</a> .
Agent/Agency	An agent is special type of company. It can be a Contract Research Organization (CRO), an U.S. agent company, or a consulting company. The agent is contracted by an authorizing/sponsoring company to file a submission to FDA on its behalf.
Application Program Interface (API)	A set of protocols and tools for building software and applications that allows different systems to communicate. Software applications use APIs to communicate with each other to exchange data, features, and functionality.
Applicability Statement 2 (AS2)	An electronic submission protocol that uses HTTP/HTTPS for electronic data exchange.
Authorization Letter	Document issued by a company that grants permission to an agent/agency to file submissions to FDA on the company's behalf.
Company	A company is a U.S. or international business entity that uses ESG NextGen to file regulatory submissions to FDA.
Dashboard	A visual interface that displays key information and metrics in a user-friendly format and is often used for monitoring system or project status.
Digital Certificate	An attachment to an electronic message that allows the recipient to authenticate the identity of the sender via third party verification from an independent certificate authority. Digital certificates are used to identify encryption and decryption codes between message senders and recipients.
ESG NextGen	The updated and modernized version of the original FDA Electronic Submissions Gateway. It introduces new business processes and new technologies to streamline the submission process, enhance the user experience and improve security.
FileCatalyst	A software solution designed for fast and secure file transfer, overcoming the limitations of traditional file transfer technologies.
Legacy ESG	The original FDA Electronic Submissions Gateway used for the submission of electronic regulatory data, prior to the introduction of ESG NextGen.
Non-Repudiation	A means to provide proof of the integrity and origin of data, both in a non-forgeable relationship that can be verified by any third party at any time, or, an authentication that, with high assurance can be assured as genuine.

Term	Definition
Non-Repudiation Letter (NRL)	Also called a Non-Repudiation Agreement. A document submitted to the FDA which certifies electronic signatures from a company's employees, agents, and/or representatives are legally binding and equivalent to traditional handwritten signatures. This letter is required for any signature on or within a submission.
Power User	A ESG NextGen role that has administrative and submission permissions in the system.
Submitter	A ESG NextGen role that can file submissions to FDA. Submitters do not have the administrative permissions of a Power User.
Transaction Partner	The entity sending submissions/communicating with the receiving and routing component (the FDA ESG NextGen) of the community.
Unified Submission Portal (USP)	An integral component of ESG NextGen that seamlessly integrates user registration, user account management, package preparation and submission, status tracking, reports and dashboards. It has a web-based user interface with a modern look and feel, leading to an improved user experience.

## Appendix 4. Acronyms

Acronym	Definition
API	Application Programming Interface
AS2	Application Statement 2
ESG	Electronic Submission Gateway
NextGen	Next Generation
FDA	Food and Drug Administration
ID	Identification
IT	Information Technology
NRL	Non-Repudiation Letter
OTP	One-Time Passcode
UAT	User Acceptance Testing
UI	User Interface
USP	Unified Submission Portal
UX	User Experience