FDA

Electronic Submission Gateway (ESG) NextGen

AS2 Setup Instructions for

Industry Users

AS2

Version 1.0

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Contents

AS2 Configuration and Submission Guide for ESG NextGen UAT

1.0 Purpose

This document provides detailed instructions for configuring and validating AS2 connections with the FDA's ESG NextGen UAT system. The guide covers updating the AS2 configuration, submitting authentication credentials, sending test submissions, and verifying receipt of necessary acknowledgements.

Your UAT participant role is critical in ensuring the successful configuration and operation of your AS2 connection in UAT, ahead of live submission. You are responsible for updating your AS2 gateway settings, submitting necessary authentication credentials, conducting test submissions, and verifying the receipt of acknowledgments (ACKs) from ESG NextGen.

2.0 Scope

This guide applies to all industry partners who currently submit to the FDA's ESG system via AS2. It is intended for use during the UAT phase. UAT testing is essential for ensuring successful transition from the legacy ESG system to ESG NextGen.

At the end of UAT, this guide will be converted for use in the live submission environment. This guide is a stand-alone document, apart from other UAT guides, to maintain clarity toward the function of AS2.

3.0 Background

The ESG NextGen system is a modernization of the FDA's Electronic Submission Gateway, designed to improve security, reliability, and performance. Industry partners are required to update their AS2 configurations to maintain connectivity and ensure the receipt of acknowledgments (ACKs).

Applicability Statement 2: A point-to-point protocol for securely exchanging data. AS2 allows businesses to transmit data, such as electronic data interchange (EDI) messages, securely and reliably. AS2 will be scheduled for retirement at a future date. Industry partners will receive ample notification before AS2 is retired.

4.0 Roles and Responsibilities

4.1 Industry Partners

Configuration Management: Update AS2 configurations to connect with the ESG NextGen UAT system.
Security Administration: Ensure that AS2 endpoints requiring authentication are configured with the correct credentials.

Testing: Conduct test submissions to validate the configuration and receipt of acknowledgments.

4.2 FDA ESG NextGen Team

Support and Guidance: Provide technical support and guidance throughout the configuration and testing process.

Validation: Process and validate submissions and authentication updates.

Confirmation: Send confirmation messages upon successful configuration updates.

5.0 Process/Procedures

5.1 Update AS2 Configuration

1. Access AS2 Configuration:

- Navigate to your AS2 gateway configuration settings.

2. Update Target URL:

- Modify the AS2 endpoint to deliver test submissions to:
  - **URL: https://upload-api-esgng-uat.preprod.fda.gov/as2/receive**
  - **Supported Ports: 443 and 4080**

3. Save and Confirm Changes:

- Save the updated configuration and ensure all changes are correctly applied.

5.2 Submit Authentication Information

This step is only required if the industry ACK AS2 endpoint is secured with a username and password. If it is not secured in this fashion please skip to section 5.3.

1. Prepare JSON Payload:

- Construct a JSON document with the following structure:

```
{
    "username": "Replace this with the username which ESG NextGen
should use to authenticate to your gateway. An empty string can be
sent to remove this if desired.",
    "password": "Replace this with the password which ESG NextGen
should use to authenticate to your gateway. An empty string can be
sent to remove this if desired.",
    "url": "Replace this with the URL of your gateway."
}
```

2. Sign the JSON Document:

- Sign the JSON payload using your regular digital certificate/key pair.

3. Send the Signed JSON:

- Submit the signed JSON via AS2 to ESG NextGen's UAT system using the Routing ID: ESGNG_ACKGATEWAY.

4. Receive Confirmation:

- ESG NextGen will validate the signature and update its configuration. A confirmation message will be sent to you.

5.3 Send a Test Submission

1. Prepare Test Submission:

- Follow your standard procedure to prepare a test submission. This will be specific to your organization.

2. Send Submission:

- Transmit the test submission to ESG NEXTGEN UAT using the updated AS2 configuration. Use either a routing ID (https://www.fda.gov/industry/about-esg/esg-appendix-j-as2-routing-ids) or headers (https://www.fda.gov/industry/about-esg/esg-appendix-f-as2-header-attributes) to indicate the receiving center and submission type.

5.4 Confirm Receipt of MDN and ACKs

1. Monitor Acknowledgements:

- Verify the receipt of the following acknowledgements via AS2:
  - MDN (Message Disposition Notification) (optional)
  - ACK1
  - ACK2
  - ACK3/4 (if applicable to your submission type)

6.0 Unchanged from Legacy ESG

The following aspects of the ESG NextGen system remain unchanged from the previous ESG system:

– The certificate used by ESG NEXTGEN to sign ACKs and decrypt submissions.
– The certificates used by industry partners to sign submissions and decrypt ACKs.
– Supported ACK types, file types, routing IDs, and routing headers.7.0 Troubleshooting

If issues arise during the configuration or submission process, verify the following:

- Correct URL, port, and routing ID configurations.
- Properly formatted and signed JSON payload.
- Accurate entry of credentials for AS2 endpoint authentication (if applicable).
- Validate your outbound firewall rules allow access to ESG NextGen. NextGen uses dynamic IP addresses so static whitelists can not be supported.

For additional support, contact the FDA ESG Help Desk at esgngsupport@fda.hhs.gov.

8.0 Risks and Mitigations

Risk: Failure to update the AS2 configuration may result in unsuccessful submission delivery and/or failure to receive ACKs.

Mitigation: Ensure all configurations are thoroughly tested in the UAT environment before production go-live.

9.0 References

FDA ESG Help Desk: esgngsupport@fda.hhs.gov

ESG NextGen Industry Landing Page: https://esgng-uat.preprod.fda.gov/portal/

10.0 Appendices

10.1 Appendix A: JSON Payload Example

```
{
    "username": "Replace this with the username which ESG NEXTGEN should
use to authenticate to your gateway. An empty string can be sent to remove
this if desired.",
    "password": "Replace this with the password which ESG NEXTGEN should
use to authenticate to your gateway. An empty string can be sent to remove
this if desired.",
    "url": "Replace this with the URL of your gateway."
}
```