



Release Configuration Sheet

LORENZ eValidator 23.2

October 2023

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1. Getting Started

1.1 Introduction

This document is the Release Configuration Sheet (RCS) for LORENZ eValidator 23.2.

The main objective of the Release Configuration Sheet is to provide an overview of the scope and impact of this release and to provide a description of the issues addressed and/or features that have been added or modified in the new version, as well as its potential impact on existing systems.

1.2 How this guide is organized

The RCS is organized in four chapters:

Chapter 1 contains general information about the release and the Release Configuration Sheet as well as an indication about expected target systems.

Chapter 2 contains the actual Release Notes including Distribution Media, Product Documentation, Release Compatibility Information and Release Impact Information.

Chapter 3 provides information about the installation process, as much as this information is of relevance to the Release Configuration Sheet.

Chapter 4 contains a description of Release Highlights and a brief narrative description of enhancements and addressed issues. Each item provides a reference to the issues tracked under [LORENZ Help Desk](#) to allow every customer to identify items fixed on their behalf.

1.3 Where this software can be installed

This software release can be installed on both client and server computers. It may be used side by side with the docuBridge client, and with the LORENZ Automator.

1.4 Installing into a validated environment

LORENZ suggests a careful analysis of the changes and/or issues of interest provided in Chapter 4 of this document, to assess necessary validation activities.

1.5 Notes

Throughout this document:

- The phrase eValidator refers to the LORENZ eValidator product.
- The phrase installation folder refers to the folder where the eValidator has been or shall be installed to (this is usually the folder named `C:\Program Files (x86)\LORENZ Life Sciences\LORENZ eValidator`).



- The phrase configuration folder refers to the folder where the eValidator configuration files have been or shall be installed to. This is the sub-folder named LORENZ Life Sciences\eValidator in the CommonAppData folder.
- The folder referred to by CommonAppData is `C:\ProgramData`.



2. Release Notes

2.1 Distribution Methods / Media

LORENZ distributes LORENZ eValidator 23.2 using the following distribution channels:

- HTTP download
- LORENZ eValidator Client update function (via LORENZ eValidator Update Service)

2.2 Product Documentation

This version of the LORENZ eValidator is created with the following documentation items:

| Documentation Item | Content |
|--|--|
| User Guide for LORENZ eValidator | This document describes how to use the LORENZ eValidator client application. |
| User Guide for LORENZ eValidator webAccess | This document describes how to use the eValidator webAccess, which provides a web browser user interface for validation tasks. This document is included in the server setup package. |
| Administrator Guide for LORENZ eValidator | This document describes how to install and configure the eValidator server components. This document is included in the server setup package. |
| Functional Specification (FSP) | This document outlines the desired features and behavior of the system. |
| Release Configuration Sheet (RCS) | This document outlines the changes in LORENZ eValidator in this release. |
| System Requirements Specification (SRS) | The SRS lists the hard- and software prerequisites for the LORENZ eValidator. |

Table 1: Product Documentation



2.3 Release Compatibility

This version will automatically replace an existing previous version of LORENZ eValidator found on the computer when you install LORENZ eValidator 23.2.

Important Release Notification for the LORENZ 23.2 Releases

Backward Compatibility

LORENZ is moving from individual products to an integrated RIM solution with multiple capabilities. An increasing number of common functionalities (e.g., controlled vocabulary management and job management) are implemented centrally and utilized by multiple capabilities. This development also results in a single harmonized installation process.

This new installation process allows installation/update of licensed capabilities (e.g., docuBridge, drugTrack and eValidator) to the newest version. Multiple capabilities with diverging versions in one environment are not allowed anymore. Therefore, for customers with multiple LORENZ capabilities in one environment, the update to 23.2 applies to all LORENZ capabilities simultaneously.

docuBridge's built-in validation requires the eValidator Server package installed. The eValidator Client package is not sufficient anymore. For compliance reasons, an exception is applicable. LORENZ eValidator 23.2 Client package can be installed on the server with a version of LORENZ docuBridge 22.x or before.

For docuBridge 23.1 installations, an eValidator RUP package will be available to apply the profile changes made with the 23.2 release also to existing 23.1 installations, without upgrading the software.

.NET and .NET Core Support Policy

LORENZ software products are based on Microsoft technology with .NET as the underlying development framework. Therefore, Microsoft .NET is one vital system environment component.

Microsoft introduced a two-year release cycle for the long-term support versions (LTS). Each LTS version (.NET 6, .NET 8, etc.) will receive updates and patches for three years.

| Version | Original release date | Release type | Support phase | End of support |
|---------|-----------------------|--------------|---------------|-------------------|
| .NET 6 | November 8, 2021 | LTS | Active | November 12, 2024 |

With the 24.1 release in April 2024, we will introduce .NET 8 as the next long term stable version of the framework.



Depending on your system environment policy, we recommend scheduling the upgrade of our software before November 12, 2024 to comply with Microsoft's .NET support.

For more information on Microsoft's .NET support policy refer to <https://dotnet.microsoft.com/en-us/platform/support/policy/dotnet-core>.

Database Scripts for UTC Time Zone Migration

LORENZ has harmonized the date time handling of the LORENZ RIM solution for the 23.2 releases. LORENZ Foundation, docuBridge and drugTrack deliver database migration scripts in their setups which convert existing date time values that are stored in the database to UTC.

It is mandatory to run these scripts during the installation of 23.2 before upgrading the database schemas of Foundation, docuBridge and drugTrack to 23.2.0.0.

The scripts are delivered with the setup package in the folder 'Database Scripts\additional\UTC Upgrade'. Further instructions about the scripts can be found in a readme file in the same folder.



3. Installation Procedure Overview

3.1 Software Installation Package

The distribution contains the software setup for LORENZ eValidator 23.2. The setup is provided as a full setup. It does not require any previous installation. If a previous version of the LORENZ eValidator is found when executing the setup, it will be updated.

3.1.1 eValidator Client Setup

This setup package installs the eValidator desktop client applications. It can be downloaded from the LORENZ web site directly.

- eValidator Client Application

This application allows verifying and validating electronic submissions purposely conforming to the ICH eCTD standard (see www.ich.org) based on configured check options and dynamic verification rules. Validation results will be created as XML and as HTML reports (optionally, also PDF); adequate XSL style sheets for viewing the report content in a web browser are also provided. LORENZ will periodically provide updates for the configuration base to keep the eValidator synchronized with the official specifications. The eValidator also supports validating certain specified non-eCTD submissions (NeeS and VNeS). For details about the predefined validation rules for non-eCTD submissions, please refer to the User Guide or the Functional Specification (FSP).

- eValidator Batch Processing Application

Like the eValidator Client Application, this application allows verifying and validating electronic submissions purposely conforming to the ICH eCTD standard (see www.ich.org) based on configured check options and dynamic verification rules. With the Batch Processing Application, you can control the validation of multiple submissions (applications, sequences, folders) through validation lists. The program is available as a separate feature in the installation package (disabled by default). Please note that an eValidator FIVE license is required to use the program.



3.1.2 eValidator Server Setup

This setup package (which is available for users with an eValidator FIVE license only) contains the eValidator server components:

- eValidator Job Runner
- eValidator webAccess

For these components, LORENZ Foundation is required.

For your convenience, the server setup package also contains the desktop client components as an optional feature to install on server systems (e.g., for remote desktop or Citrix).

If you want to use the eValidator as part of the publishing task from within your docuBridge 23.2 system, you need to install the eValidator Server Setup on the Foundation server.

3.2 License Types

For the LORENZ eValidator different license types are available:

3.2.1 eValidator Basic License

This is a free of charge license which allows running validations for eCTD or non-eCTD submissions. Several features have been disabled for this license type:

- You cannot use customized profiles or change the report branding text and logo.
- The use of the LORENZ eValidator Batch Processing client is not supported.
- You cannot change the user interface language.
- You cannot create or use custom profiles.
- You cannot change any severity settings for the validation rules.
- You cannot change any rule parameters in a loaded profile.
- You cannot change the profile you have selected at the first start of the software. Only reinstalling the software will allow re-selecting the profile.
- Only one instance of the LORENZ eValidator program can be used at a time.
- If you are using a “branded” version of the eValidator (such as CDE Validator), changing the profile is limited to the region-related profiles.
- You cannot validate submissions on a server operating system such as Microsoft Windows Server 2016, 2019, or 2022.
- The eValidator PowerShell host is not supported.
- You will not get the summary report in addition to the full validation report.
- You cannot use parallel execution of validation rules to improve the overall performance for large submissions.
- Profile content reports are not available.
- You cannot use “Baseline Optimized Validation”.



- eValidator REST Service is not available.
- eValidator webAccess is not available.
- Advertisement screens will be displayed during when starting the application and when starting a validation.

3.2.2 eValidator ONE License

This license provides the same features as the Basic version plus the option to switch between profiles (regions) without reinstalling the software. The other limitations of the Basic license are still effective.

The license can be purchased online at <https://www.lorenz.cc/Solutions/eValidator/>.

3.2.3 eValidator FIVE License

This license (previously named “eValidator Enterprise”) does not have the functional limitations of the eValidator Basic or eValidator ONE license.

Please note:

The available extended profiles may depend on the modules you purchased. For detailed information please contact LORENZ Sales or speak with your LORENZ Account Manager

The eValidator webAccess can be used with any eValidator FIVE license.

3.3 New/Update Installation

Before installing LORENZ eValidator, please unzip the distribution file to a temporary directory.

Please check the System Requirements Specification document before installing the update. The setup will refuse to start on no longer supported operating systems (e.g., Windows 7 and Windows Server 2008).

3.3.1 eValidator Client Setup

Please follow these steps to perform the installation:

1. In case Windows Installer or Microsoft .NET 4.7.2 runtime cannot be found, these components will not be installed automatically. You need to do this manually before you start the installation of the eValidator.
2. Start the file **Setup.msi** from the extracted distribution content.
3. Acknowledge the confirmation dialogs and follow the instructions on the screen. Completing the installation of these components might require restarting the computer.



4. Please acknowledge the **User Account Control** message only if the verified publisher is "LORENZ Bridge Software GmbH". You can click on **Show details** to see additional information about the publisher's identity.
5. Follow the instructions displayed to complete the installation. For a quick and easy procedure, it is recommended to accept the default settings provided by the wizard.
6. Desktop shortcuts and new start menu items will be created. These shortcuts can be used to start the application.
7. After starting the eValidator client application, you can select the profile you want to use for your validation(s). Profiles contain collections of validation rules and settings for a specific validation scope (e.g., submitting an application to the US FDA or to Health Canada). The LORENZ eValidator installs a set of different profiles you can choose from.

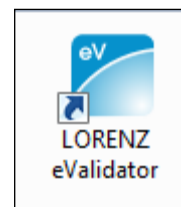


Figure 1: Shortcut

Please note: With a Basic license, the profile chosen by the user who ran the application cannot be changed and will also apply to all other users accessing the installation. To select another profile, please re-install your eValidator Basic.

The FIVE and ONE licenses allow switching profiles (File > Open Profile > Select & OK or Double-click on desired profile). The next time you start the LORENZ eValidator, the last used profile will be loaded again automatically.



Figure 2: Profile Selection Dialog



3.3.2 eValidator Server Setup

Please follow these steps to perform the installation:

1. In case Windows Installer or Microsoft .NET 4.7.2 runtime cannot be found, these components will not be installed automatically. You need to do this manually before you start the installation of the eValidator.
2. Start the file **Setup.msi** from the extracted distribution content.
3. Acknowledge the confirmation dialogs and follow the instructions on the screen. Completing the installation of these components might require restarting the computer.
4. From the **Feature selection** dialog, choose the components you want to install, and click **Next**. The available features depend on whether you are installing the eValidator Client or eValidator Server package.

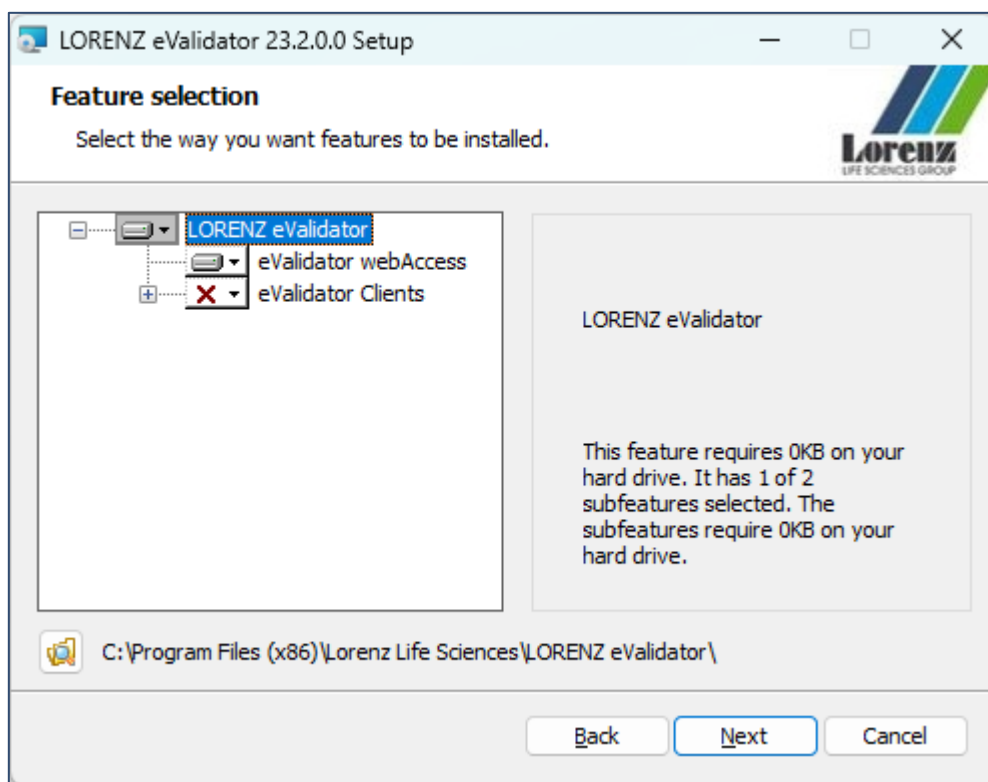


Figure 3: Server Setup

Currently, the eValidator webAccess feature cannot be unselected in the setup. If you do not want to use eValidator webAccess in your environment, please complete the installation first and then refer to the eValidator Administrator Guide, section 4.2.

5. The eValidator installation wizard will be started.
6. Please acknowledge the **User Account Control** message only if the verified publisher is "LORENZ Bridge Software GmbH". You can click on **Show details** to see additional information about the publisher's identity.



7. Follow the instructions displayed to complete the installation. For a quick and easy procedure, it is recommended to accept the default settings provided by the wizard.

3.3.3 Silent Installations

For a **silent installation** through the Windows Installer, the following parameters can be used with the **msiexec** command.

3.3.3.1 Client Setup

```
msiexec /quiet /i {Path to setup.msi}
```

This will install the standard eValidator client application only.

```
msiexec /quiet /i {Path to setup.msi} ADDLOCAL=ALL
```

This will install the eValidator client application and the eValidator Batch Processing client application.

3.3.3.2 Server Setup

```
msiexec /quiet /i {Path to setup.msi}
```

This will install the eValidator webAccess and the eValidator job runner components.

```
msiexec /quiet /i {Path to setup.msi} ADDLOCAL=ALL
```

This will install all components and features (incl. the client applications).

For individual selection, the optional feature names are as follows (only the eValidator client components are optional):

```
F_eValidatorClient_DoInstall  
F_BatchProcessing_DoInstall
```

For the credentials to run the “LORENZ SubmissionValidationServices”:

```
SVC_ACCOUNT=AccountName SVC_PASSWORD=Password
```




3.3.4 Customizing the Setup before Roll-Out

If the eValidator Setup is executed, it checks for a folder named **eValidatorConfig** existing in the same folder as the setup is located. If the folder exists, all files in this folder will be copied to **C:\ProgramData\Lorenz Life Sciences\eValidator** as the final step of the installation. With this approach it is possible to apply a license and/or custom configuration settings or install a custom version of a profile. Example:

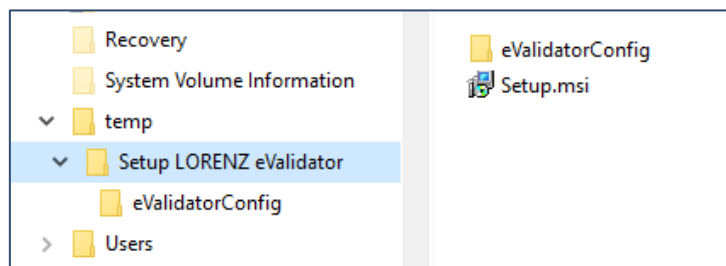


Figure 4: Customizing Setup

In the eValidatorConfig folder, you can place a customized copy of the system.config file, e.g., to preset the serial number for the license so users won't have to activate the license upon first start of the program. In addition, the license file itself can also be placed here. Both files will then be copied to the destination folder **C:\ProgramData\Lorenz Life Sciences\eValidator**, overwriting any already existing files with the same name.

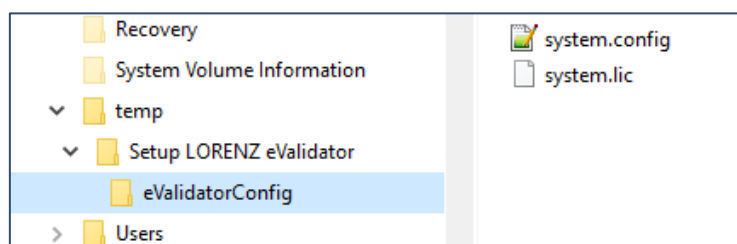


Figure 5: Customizing Setup - Example



4. Changes in the eValidator 23.2 Release

4.1 eValidator Profiles

4.1.1 CA eCTD

| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|---|
| EVA-4881 | Critical | Bug | CA eCTD Validation Criteria 5.1 Validation Rule C05 The path length counting must start with the application folder name. However, the profiles were configured to start counting after the application folder name. This means that not all invalid cases were detected. The issue has now been resolved. |
| EVA-4781 | Major | Bug | CA eCTD Validation Criteria 5.1 Validation Rule F09 Rule F09 reported an error if a straight apostrophe (') instead of a single right quotation mark was being used in the sequence description. This has been resolved now. |
| EVA-4615 | Minor | Feature | CA eCTD Validation Criteria 5.1 Rules B12 and B23 The subject text for rule B12 has been adjusted to Documents with bookmarks . The subject text for rule B13 has been adjusted to Documents with links . |

| Change Impact | Description |
|---------------------|---|
| Profiles | <ul style="list-style-type: none"> CA eCTD - Validation Criteria 5.1 CA eCTD - Validation Criteria 5.1 EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|-------------|
| IQ | n/a |
| OQ | n/a |



| Validation Impact | Description |
|-------------------|---|
| PQ | <p>EVA-4881: If you observed an issue with rule C05 not reporting a path that was too long, please re-validate to verify that the issue has been resolved.</p> <p>EVA-4781: If you observed an issue with rule F05 reporting an error about a sequence description with single quotation marks, please re-validate to verify that both straight and right quotation marks will be accepted now. Hint: Please make sure to always use the latest Regulatory Transaction Matrix provided by Health Canada.</p> <p>EVA-4615: This has no impact on actual validation results. PQ update should therefore not be necessary.</p> |



4.1.2 ECOWAS eCTD

| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|--|
| EVA-4486 | Major | Feature | ECOWAS eCTD Validation Criteria 1.0 A new profile has been added for the validation of ECOWAS eCTD submissions, using validation criteria version 1.0. This is for testing purposes only, based on the content published on this website: https://ectd.wahooas.org/ |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> ECOWAS-WAHO eCTD Validation Criteria v1.0 ECOWAS-WAHO eCTD Validation Criteria v1.0, EXTENDED |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|---|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-4486: Please verify that the ECOWAS eCTD profile is available in eValidator desktop client, eValidator webAccess, and LORENZ Job Management. |



4.1.3 ECOWAS eSubmission

| Ticket Number | Priority | Type | Description |
|----------------------------------|----------|---------|--|
| EVA-4746 EVA-4848 EVA-4787 | Major | Feature | ECOWAS eSubmission Validation Criteria 1.0 A new profile has been added for the validation of ECOWAS eSubmission (non eCTD), using validation criteria version 1.0. This is for testing purposes only, based on the content published on this website: https://ectd.wahooas.org/ |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> • ECOWAS-WAHO eSub Validation Criteria v1.0 • ECOWAS-WAHO eSub Validation Criteria v1.0, EXTENDED |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-4746, EVA-4848, EVA-4787: Please verify that the ECOWAS eSubmission profile is available in eValidator desktop client, eValidator webAccess, and LORENZ Job Management. |



4.1.4 EU eCTD

| Ticket Number | Priority | Type | Description |
|---------------|----------|------|---|
| EVA-4543 | Major | Bug | <p>EU eCTD PDF Reports</p> <p>For an EU eCTD submission, the validation report in PDF format could not be generated if rule 15.BP3 had any findings reported related to non-eAF documents not named like form-annex.pdf in section 12-form. This has now been resolved. The HTML report was not affected by this issue.</p> <p>This update was already available with the regulatory update package 1.11.2.</p> |
| EVA-4539 | Major | Bug | <p>EU eCTD Validation Rule 11.12</p> <p>A <code>delete</code> operation on a leaf that was already replaced by another leaf was not reported by rule 11.12 in the EU eCTD profile. This has now been resolved.</p> <p>This update was already available with the regulatory update package 1.11.2.</p> |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> EU eCTD Validation Criteria 7.1 EU eCTD Validation Criteria 7.1, EXTENDED |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|-------------|
| IQ | n/a |
| OQ | n/a |



| Validation Impact | Description |
|-------------------|---|
| PQ | <p>EVA-4539:</p> <p>The issue has been detected by LORENZ. No customer has reported this so far. The correction applies to delete operations only. A replace operation on a leaf that was already replaced by another leaf (or deleted) has been reported correctly.</p> <p>To verify the correctness of the implementation, use a sample submission with at least 3 sequences:</p> <ul style="list-style-type: none">- In the first sequence, use a leaf to add a new document.- In the second sequence, use a leaf to replace the document from the first sequence.- In a third sequence, use a leaf to delete the document from the first sequence. <p>EVA-4543:</p> <p>To verify the correctness of the implementation, add a file eaf-test.pdf in section 12-forms (through a leaf element in eu-regional.xml). The eaf-test.pdf document must not be an eAF (neither a PDF form nor a DADI generated eAF). Perform the validation on the sequence, with Generate PDF Report selected. Verify that rule 15.BP3 reports a finding and eVReport.pdf is available.</p> |



4.1.5 EU VNeS

| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|--|
| EVA-4913 | Major | Feature | EU VNeS 3.1 New validation profiles have been added for the validation of EU VNeS 3.1 submissions (Pharmaceutical, Immunological, MRL, Biological). The previous version 3.0 profiles have been moved to the "Expired" folder. |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> • VNeS 3.1, biological • VNeS 3.1, immunological • NeeS 3.1, pharmaceutical • VNeS 3.1, MRL |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|---|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-4913: Please verify that the listed profiles are available and can be used with Basic, ONE, or FIVE licenses in the eValidator appliances. |



4.1.6 JP eCTD 4.0

| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|--|
| EVA-4846 | Major | Feature | <p>JP eCTD 4.0, Validation Criteria 1.5.0.1 JP-eCTD4-049, JP-eCTD4-100, JP-eCTD4-137</p> <p>The rules listed above will now report errors when a codeSystem is not valid for the date of the submission. By default, the submission date will be assumed as today. Alternatively, the date of the submission can be provided in the system.config file though the runtime variable r_submission_date. Format is yyyyMMdd. When the value is empty or not provided, the submission date will be set to today.</p> |
| EVA-4895 | Major | Feature | <p>JP eCTD 4.0, Validation Criteria 1.5.0.1</p> <p>To avoid possible conflicts between predefined OIDs for codeSystems and sponsor-defined OIDs, the logic to identify predefined OIDs has been improved. It will now consider all OIDs as predefined (by ICH or PMDA) that have an exact match in the published CV files. Previously, the detection was based on substring comparison only (any OID that started with 2.16.840.1.113883.3.989 was considered predefined by ICH or PMDA).</p> |
| EVA-4815 | Major | Bug | <p>JP eCTD 4.0 - Validation Criteria 1.5.0.1 Rule JP-eCTD4-135</p> <p>For sequences with many contextOfUse elements, executing rule JP-eCTD4-135 took very long. This has now been improved. The rule results will always be available after a few seconds only.</p> |
| EVA-4497 | Major | Bug | <p>JP eCTD 4.0 - Validation Criteria 1.5.0.1</p> <p>Several issues have been resolved related to the use of sponsor-defined keyword code system when the codeSystem ID was using an OID that started with 2.16.840.1.113883.3.989.</p> <p>JP-eCTD4-137: The rule's implementation did not detect incomplete OIDs (if the OID started with 2.16.840.1.113883.3.989, it passed)</p> <p>JP-eCTD4-135: The rule's implementation did not consider the OID version number to check the code validity. if the OID started with 2.16.840.1.113883.3.989, any code from any JP regional or ICH CV was accepted.</p> <p>JP-eCTD4-141: There were issues with incomplete OIDs. For example, when two keywords had an OID with a missing version number, the error message</p> |



| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|---|
| | | | <p>mentioned a keyword type that was not correct in this case.</p> <p>JP-eCTD4-118: There were issues with incomplete OIDs. For example, when a keyword in the new contextofUse had an OID with a missing version number, the error message mentioned a keyword type that was not correct in this case.</p> |
| EVA-4792 | Minor | Bug | <p>JP eCTD 4.0 - Validation Criteria 1.5.0.1</p> <p>In the Japanese translation, the validation criteria group title for the Packages section incorrectly contained the version 1.4.0.1. This has now been corrected.</p> |
| EVA-4544 | Major | Feature | <p>JP eCTD 4.0, Validation Criteria 1.5.0.1</p> <p>PMDA has published new validation criteria version 1.5.0.1 for Japanese eCTD 4.0 submissions. The validation profile has been updated accordingly. The following changes were made:</p> <ul style="list-style-type: none"> • The profile is now referencing validation criteria version number 1.5.0.01 instead of 1.4.0.1 • JP-eCTD4-299 has been removed • For the following rules, the ampersand (&) character will now be accepted when used in escape sequences for the otherwise invalid characters < , > , " (double quotes), &. JP-eCTD4-102, JP-eCTD4-206, JP-eCTD4-217, JP-eCTD4-232, JP-eCTD4-283, JP-eCTD4-310, JP-eCTD4-326, JP-eCTD4-329, JP-eCTD4-334 <p>This update was already available with the regulatory update package 1.11.2.</p> |
| EVA-4540 | Major | Bug | <p>JP eCTD 4.0 - Validation Criteria 1.5.0.1</p> <p>No findings were reported by following rules even if the path length was exceeded:</p> <p>JP-eCTD4-051, JP-eCTD4-078, JP-eCTD4-103, JP-eCTD4-207, JP-eCTD4-218, JP-eCTD4-233, JP-eCTD4-252, JP-eCTD4-284, JP-eCTD4-307, JP-eCTD4-311, JP-eCTD4-327, JP-eCTD4-330, JP-eCTD4-335</p> <p>This has now been resolved.</p> <p>This update was already available with the regulatory update package 1.11.2.</p> |



| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|--|
| EVA-4499 | Minor | Bug | <p>JP eCTD 4.0 - Validation Criteria 1.5.0.1 JP-eCTD4-097</p> <p>For a contextOfUse with statusCode “suspended”, the rule was not working properly. For those CoUs, the validation profile inadvertently used the result from the submissionUnit/code/@codeThat means, if submissionUnit/code/@code had a wrong code, it would also be reported at JP-eCTD4-097, referring to the CoU with statusCode “suspended”. This has now been resolved.</p> <p>Please verify that for CoUs with statusCode “suspended” no errors will be triggered at JP-eCTD4-097 (not duplicating errors reported by JP-eCTD4-075).</p> <p>This update was already available with the regulatory update package 1.11.1.</p> |
| EVA-4504 | Major | Bug | <p>JP eCTD 4.0 - Validation Criteria 1.4.0.1 CV Update</p> <p>The regular 3-month-update (released April 26) of the Japanese CV files has been added to the eValidator configuration.</p> <p>This update was already available with the regulatory update package 1.11.1.</p> |
| EVA-4500 | Major | Bug | <p>JP eCTD 4.0 - Validation Criteria 1.4.0.1 Rules JP-eCTD4-148 and JP-eCTD4-149</p> <p>For a contextOfUse with statusCode “suspended”, the rules incorrectly triggered an error. This has now been resolved.</p> <p>This update was already available with the regulatory update package 1.11.1.</p> |
| EVA-4739 | Major | Feature | <p>JP eCTD 4.0, Validation Criteria 1.5.0.1</p> <p>The regular 3-month-update (released June 30) of the Japanese CV files has been added to the eValidator configuration. Please verify that the Code jp_sdtm_20230630 has been added to JP Terminology (Tabulation) CV. The Code jp_adam_20230630 has been added to JP Terminology (Analysis) CV.</p> |



| Ticket Number | Priority | Type | Description |
|---------------|----------|------|--|
| | | | This update was already available with the regulatory update package 1.11.3. |

| Change Impact | Description |
|---------------------|---|
| Profiles | <ul style="list-style-type: none"> Japan (PMDA) - eCTD 4.0 |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|---|
| IQ | n/a |
| OQ | n/a |
| PQ | <p>EVA-4846: Introducing a submission date was necessary because PMDA has posted expiration dates for certain code system versions. Currently, the submission date is assumed to be the same as the date of the validation. With future update packages, it will be possible to specify a submission date in eValidator webAccess and LORENZ Job Management. IN the meantime, you can provide a submission date in the system.config file if needed.</p> <p>EVA-4895, EVA-4497: Please make sure not to use OIDs for sponsor-defined code-systems that conflict with OIDs for pre-defined OIDs from ICH or regional authorities. Otherwise, the validation might result in multiple errors.</p> <p>EVA-4815, EVA-4792: This does not change the validation results. PQ update should not be necessary.</p> <p>EVA-4544: Please verify that the new profile for validation criteria version 1.5.0.1 is available in the selection list (in the desktop clients and/or the LORENZ Job Management and eValidator webAccess). The profile for the previous version 1.4.0.1 of the validation criteria has been replaced by the new profile.</p> |



| Validation Impact | Description |
|-------------------|--|
| | <p>EVA-4540: The regular expressions used to check the path lengths were incorrect. To verify that the changes are correct, please add a text that exceeds the defined maximum length for the items referenced by the validation rules listed above. For example (rule JP-eCTD4-206) the manufactured product name: manufacturedProduct/name/part/@value</p> <p>EVA-4499: Please verify that for CoUs with statusCode "suspended" no errors will be triggered at JP-eCTD4-148 or JP-eCTD4-149.</p> <p>EVA-4504: Please verify that the Code "jp_sdtm_20230331" has been added to JP Terminology (Tabulation) CV. And The Code "jp_adam_20230331" has been added to JP Terminology (Analysis) CV.</p> <p>EVA-4500: Please verify that for CoUs with statusCode "suspended" no errors will be triggered at JP-eCTD4-097 (not duplicating errors reported by JP-eCTD4-075).</p> <p>EVA-4739: Verify that the Code jp_sdtm_20230630 has been added to JP Terminology (Tabulation) CV and the Code jp_adam_20230630 has been added to JP Terminology (Analysis) CV.</p> |



4.1.7 MD5 Proofreading and Correction Profile

| Ticket Number | Priority | Type | Description |
|---------------|----------|------|--|
| EVA-4790 | Major | Bug | With offline mode activated, the Proofreading and Correction profile sometimes replaced the DTD reference in the us-regional.xml with a local file path. This happened when any checksum needed to be corrected. The issue has now been resolved. |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> eCTD MD5 Proofreading and Correction |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | <p>EVA-4790:</p> <p>This profile requires an eValidator FIVE license.</p> <p>Customers how have been using this profile should check that the activated offline mode will not lead to a modified DTD reference when applying the profile to a US eCTD 3.2 submission sequence.</p> |



4.1.8 SG eCTD

| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|---|
| EVA-4479 | Major | Feature | <p>SG eCTD Validation Criteria 0.9</p> <p>A new profile has been added for the validation of Singapore eCTD submissions according to validation criteria version 0.9.</p> <p>Please verify that the profiles for Singapore eCTD are now available in the eValidator desktop client, in LORENZ Job Management, and in eValidator webAccess (depending on which components have been installed).</p> <p>This update was already available with the regulatory update package 1.11.1.</p> |
| EVA-4554 | Minor | Bug | <p>SG eCTD Validation Criteria 0.9, Rule 2.2.1</p> <p>According to the description text for validation rule 2.2.1, the path length check should start with the first character of the application folder. However, the profile incorrectly started counting with the sequence folder. This has now been resolved.</p> <p>This update was already available with the regulatory update package 1.11.2.</p> |
| EVA-4528 | Minor | Bug | <p>SG eCTD Validation Criteria 0.9, Rules 4.8.1-4.8.3</p> <p>The submission content checks 4.8.1 - 4.8.3 must be executed for initial sequences only. The validation profile used an incorrect condition so that the checks were executed for non-initial sequences but not for initial sequences. This has now been resolved.</p> <p>This update was already available with the regulatory update package 1.11.2.</p> |



| Change Impact | Description |
|---------------------|---|
| Profiles | <ul style="list-style-type: none">SG eCTD - Validation Criteria v0.9SG eCTD - Validation Criteria v0.9, EXTENDED |
| Configuration Files | No changes |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | <p>EVA-4479: Please verify that the profiles for Singapore eCTD are now available in the eValidator desktop client, in LORENZ Job Management, and in eValidator webAccess (depending on which components have been installed). Please note that validation criteria version 0.9 is for testing purposes only. The final version will be published by HSA in 2024.</p> <p>EVA-4554: Please verify in PQ the path length check is now starting with the application folder. Please also note that validation criteria version 0.9 is for testing purposes only. The final version will be published by HSA in 2024.</p> <p>EVA-4528: Please check with PQ that the content verification will now be applied to initial sequences only. Please also note that validation criteria version 0.9 is for testing purposes only. The final version will be published by HSA in 2024.</p> |



4.1.9 TW eCTD

| Ticket Number | Priority | Type | Description |
|---------------|----------|------|---|
| EVA-4886 | Major | Bug | TW eCTD Validation Criteria eCTD-V-R1 The additional checks that apply to the extended TW profile only were also displayed in the standard profile. This issue has been resolved now. |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> TW eCTD - Validation Criteria eCTD-V-R1 TW eCTD - Validation Criteria eCTD-V-R1, EXTENDED |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|--|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-4886: Please verify that the standard profile now only contains the official rules as posted by the Taiwan FDA. |



4.1.10 US eCTD (M1 v2.5, DTD v3.3)

| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|--|
| EVA-4795 | Critical | Feature | US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 The validation for grouped and non-grouped US eCTD 3.2 submissions does no longer send requests to the FDA servers to avoid issues with the FDA blacklisting machines that are sending too many requests. |
| EVA-4489 | Major | Feature | US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 Validation Rule 5038 5038 should not report an error when 2252 is not a fillable form. Only code 7 should trigger. This has now been corrected. |
| EVA-4861 | Major | Bug | US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 Validation Rule 2025 The implementation logic for secondary applications in a grouped submission was incorrect. This has been resolved now. This affects the profile Profile_US_4-4_GroupedChild.xml only (including the extended version of it). |
| EVA-4557 | Major | Bug | US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 Validation Rule 1154 The rule's implementation did not report an error when a document was replaced or deleted in a grouped submission and for one or more secondary applications in the group, the original document was unknown because those applications were not part of the group at the time the original document was added. This has now been resolved. |
| EVA-4822 | Major | Bug | US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 Validation Rule 2001 Reverting from eCTD 4.0 to eCTD 3.2 is not allowed: If the application folder contains any sequences with eCTD 4.0 format, rule 2001 will now report an error. |
| EVA-4574 | Major | Bug | US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 Formatting and typographical errors have been corrected in validation criteria description texts in the report. |
| EVA-4613 | Major | Bug | US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 When using the extended profile for US eCTD 3.2 submissions (DTD 3.3, M1 v2.5), the description texts for the extended checks were missing in the validation results in Submission Repository. This has now been resolved. |



| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|--|
| EVA-4871 | Minor | Feature | <p>US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 Extended Profile Rule PDF_012</p> <p>PDF_012 will now exempt files from the literature reference folders 33-lit-ref, 43-lit-ref, and 54-lit-ref. Note that physical folders should be named according to ICH recommendations for this rule to work correctly.</p> |
| EVA-4522 | Minor | Bug | <p>US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 Rule 1238</p> <p>The description for rule 1238 has been adapted. The new description is: <i>The file size exceeds the maximum limit (400 MB). Note: This limit may not be applicable if your file is a dataset. Please refer to the Study Data Technical Conformance Guide document for current information regarding dataset file sizes.</i></p> |
| EVA-4743 | Major | Feature | <p>US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 Validation Rule 2021</p> <p>For a sequence that uses Correspondence (fdasst7) as submission sub-type, the eValidator will now report a medium-level finding with rule 2021 if this sub-type was already used before in the same regulatory activity. Please note: The corresponding problem description in the posted US FDA validation criteria does not include Correspondence in the in the list of affected submission sub-types. However, since Correspondence must only be to be used to start a new regulatory activity for submission type Product Correspondence, it should also be in scope of rule 2021. This has been confirmed by the US FDA.</p> <p>This update was already available with the regulatory update package 1.11.3.</p> |



| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|---|
| EVA-4744 | Major | Feature | <p>US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4 Validation Rule 2025</p> <p>Implementation logic of the rule has been corrected.</p> <p>Sequences where the sequence number and the submission-id do not match will report a finding of the combination of submission type and submission sub-type is one of the following (indicating the start of a new regulatory activity):</p> <ul style="list-style-type: none"> • Original Application / Application • Efficacy Supplement / Application • Chemistry Manufacturing Controls Supplement / Application • Labeling Supplement / Application • Annual Report / Report • Product Correspondence / Correspondence • Postmarketing Requirements or Postmarketing Commitments / Original • Promotional Labeling Advertising / Original • IND Safety Reports / Report • Periodic Safety Reports / Report • REMS Supplement / Application <p>(Note: Pairing with submission sub-type Presubmission will not be checked here because it can be used more than once per regulatory activity)</p> <p>Sequences where the sequence number and the submission-id match will report a finding if the combination of submission type and submission sub-type is not one of the pairings listed above or:</p> <ul style="list-style-type: none"> • Original Application / Presubmission • Efficacy Supplement / Presubmission • Chemistry Manufacturing Controls Supplement / Presubmission • Labeling Supplement / Presubmission <p>This update was already available with the regulatory update package 1.11.3.</p> |



| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|--|
| EVA-4576 | Critical | Feature | <p>US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4</p> <p>When using the extended profile, multiple calls to the FDA server could lead to denied access (blacklisting). This has now been resolved. The number of calls to the server has been optimized.</p> <p>This update was already available with the regulatory update package 1.11.3.</p> |
| EVA-4570 | Minor | Feature | <p>US FDA eCTD 3.2 M1 v2.5 Validation Criteria 4.4</p> <p>When performing a validation, the eValidator tries to download the current versions of the CV files from the FDA server (application types, submission types, etc.). If the download for one or more of those files fails, the eValidator will now use a local copy instead (from its configuration folder that has been installed with the setup).</p> <p>This update was already available with the regulatory update package 1.11.3.</p> |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> US eCTD - Val. Crit. 4.4 (CDER) US eCTD - Val. Crit. 4.4 (CDER), EXTENDED US eCTD - Val. Crit. 4.4 (CBER) US eCTD - Val. Crit. 4.4 (CBER), EXTENDED US eCTD - Val. Crit. 4.4 (CDER) - Grouped Secondary Application US eCTD - Val. Crit. 4.4 (CDER) - Grouped Secondary Application, EXTENDED US eCTD - Val. Crit. 4.4 (CBER) - Grouped Secondary Application US eCTD - Val. Crit. 4.4 (CBER) - Grouped Secondary Application, EXTENDED |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|---|
| OQ/PQ | <p>EVA-4795:</p> <p>Validating US eCTD 3.2 submissions should now also be possible without an active internet connection, like using the offline mode.</p> |



| Validation Impact | Description |
|-------------------|--|
| | <p>EVA-4489: This may result in a different number of findings compared to the previous release: Rule 5038 will no longer trigger in the described scenario. But since high-error rule 7 will still trigger, there is no actual change in the validation outcome (it would still fail).</p> <p>EVA-4861: Please note that rule 2025 is not officially effective yet. But it is important to follow the regulations.</p> <p>EVA-4557: Rule 1154 is medium-level severity. Customers should update their PQ to verify that the described scenarios will now trigger findings in the validation.</p> <p>EVA-4822: Please note that eCTD 4.0 support has been implemented for testing purposes. As of now (November 2023), the US FDA does not yet accept eCTD 4.0 submissions. Therefore, this change will become relevant in future and there should be no PQ update required yet.</p> <p>EVA-4574: This does not affect the validation results. PQ update should not be necessary.</p> <p>EVA-4613: This only affected extended profiles and only if validation was executed in docuBridge Submission Repository. Actual validation results in the reports were not affected.</p> <p>EVA-4871: This applies to the extended profile only. Customers who experienced warnings in the report for any larger literature reference documents not having bookmarks should verify that those documents will no longer be reported by PDF_012. This will only work if the literature reference folder names recommended by ICH are used.</p> <p>EVA-4522: This does not affect the validation results. PQ update should not be necessary.</p> <p>EVA-4743: Verify that a medium level finding will be reported for rule 2021, when the Correspondence submission sub-type was already used before in the same regulatory activity.</p> <p>EVA-4744: Verify a finding is reported when sequence number and the submission-id do not match in one of the following combinations of submission type and submission sub-type:</p> <ul style="list-style-type: none"> - Original Application / Application - Efficacy Supplement / Application - Chemistry Manufacturing Controls Supplement / Application - Labeling Supplement / Application - Annual Report / Report - Product Correspondence / Correspondence - Postmarketing Requirements or Postmarketing Commitments / Original |



| Validation Impact | Description |
|-------------------|---|
| | <ul style="list-style-type: none">- Promotional Labeling Advertising / Original- IND Safety Reports / Report- Periodic Safety Reports / Report- REMS Supplement / Application <p>Verify a finding is reported when sequence number and the submission-id match in a combination not listed above or one of the following combinations of submission type and submission sub-type:</p> <ul style="list-style-type: none">- Original Application / Presubmission- Efficacy Supplement / Presubmission- Chemistry Manufacturing Controls Supplement / Presubmission- Labeling Supplement / Presubmission <p>EVA-4576: The validation rules in the extended profile that caused the excessive calls to the US FDA server were A-M1_LC1, A-M1_LC2, A-M1_LC3, A-M1_LC4, A-M1_LC6, and A-M1_LC6. For those rules, no calls to the FDA server will be made anymore.</p> <p>EVA-4570: There should be no need for PQ-related updates for this. Customers who nevertheless want to add in-depth tests to verify this as part of their system validation should contact LORENZ for assistance.</p> |



4.1.11 US eCTD 4.0

| Ticket Number | Priority | Type | Description |
|---------------|----------|------|---|
| EVA-4829 | Major | Bug | <p>US FDA eCTD 4.0 Validation Criteria 1.2 US-eCTD4-322</p> <p>When a previous sequence existed as a secondary application sequence in a grouped submission where the primary application sequence was using eCTD 3.2 format, the rule US-eCTD4-322 did not trigger an error when the submission was validated through the docuBridge Submission Repository. This has now been resolved.</p> |
| EVA-4497 | Major | Bug | <p>US FDA eCTD 4.0 Validation Criteria 1.2</p> <p>Several issues have been resolved related to the use of sponsor-defined keyword code system when the codeSystem ID was using an OID that started with 2.16.840.1.113883.3.989.</p> <p>eCTD4-031: The rule's implementation did not detect incomplete OIDs (if the OID started with 2.16.840.1.113883.3.989, it passed).</p> <p>eCTD4-032: ICH or US FDA defined keywords: The validation did not consider the OID version number to check the code validity. If the OID started with "2.16.840.1.113883.3.989", any code from any regional or ICH CV was accepted. Sponsor-defined Keywords: When a sponsor-defined codeSystem started with 2.16.840.1.113883.3.989, false positives were reported with eCTD4-032.</p> <p>eCTD4-071: ICH or US FDA defined keywords: When the OID was not complete (but started with 2.16.840.1.113883.3.989), the error message was incorrect. The keyword type mentioned in the message was wrong. Furthermore, it did not detect OIDs with invalid version numbers. Sponsor-defined Keywords: When a sponsor-defined codeSystem started with 2.16.840.1.113883.3.989, false positives were reported with eCTD4-071.</p> <p>eCTD4-070: ICH or US FDA defined keywords: The rule's implementation did not detect incomplete OIDs with missing version numbers. Any version was accepted, even invalid ones.</p> <p>eCTD4-072: There were issues with incomplete OIDs. For example, when two keywords</p> |



| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|--|
| | | | <p>had an OID with a missing version number, the error message mentioned a keyword type that was not correct in this case.</p> <p>eCTD4-025: There were issues with incomplete OIDs. For example, when a keyword in the new contextofUse had an OID with a missing version number, the error message mentioned a keyword type that was not correct in this case. Sponsor-defined Keywords: When a sponsor-defined codeSystem started with 2.16.840.1.113883.3.989, false positives were reported with eCTD4-070 about keyword mismatches in the replace operation.</p> |
| EVA-4812 | Minor | Bug | <p>US FDA eCTD 4.0 Validation Criteria 1.2 eCTD4-322</p> <p>Rule eCTD4-322 returned an unexpected output text ("Do nothing") in the report when the rule passed without findings. This issue has now been resolved.</p> |
| EVA-4575 | Minor | Bug | <p>US FDA eCTD 4.0 Validation Criteria 1.2</p> <p>Formatting and typographical errors for the validation criteria description texts in the report have been corrected.</p> |
| EVA-4336 | Major | Feature | <p>US FDA eCTD 4.0 Validation Criteria 1.2 eCTD4-038</p> <p>This rule will now also report an error when the attribute application.id.item@root is present but has an empty value.</p> <p>This update was already available with the regulatory update package 1.11.3.</p> |
| EVA-4523 | Minor | Bug | <p>US FDA eCTD 4.0 Validation Criteria 1.2 US-eCTD4-555</p> <p>For non-clinical studies, the report output for US-eCTD4-555 had the correct number of findings but the text in the report was incomplete. This has now been resolved.</p> <p>This update was already available with the regulatory update package 1.11.2.</p> |
| EVA-4521 | Minor | Bug | <p>US FDA eCTD 4.0 Validation Criteria 1.2 US-eCTD4-536</p> |



| Ticket Number | Priority | Type | Description |
|---------------|----------|------|---|
| | | | <p>Documents in 1.14, 1.15 and aCRFs (annotated CRFs) were not exempt from the check in the implementation of US-eCTD4-536. This has now been resolved.</p> <p>This update was already available with the regulatory update package 1.11.2.</p> |
| EVA-4498 | Major | Bug | <p>US FDA eCTD 4.0 Validation Criteria 1.2 US-eCTD4-075</p> <p>Rule eCTD4-075 reported errors for Context of Use elements with status suspended. However, for those elements, no code information is required. This has now been resolved.</p> <p>This update was already available with the regulatory update package 1.11.1.</p> |

| Change Impact | Description |
|---------------------|---|
| Profiles | <ul style="list-style-type: none"> US - eCTD 4.0 |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|---|
| OQ/PQ | <p>Please note that eCTD 4.0 support has been implemented for testing purposes. As of now (October 2023), the US FDA does not yet accept eCTD 4.0 submissions.</p> <p>EVA-4829: Please note that such grouped submission scenarios can only be handled when validation is executed in docuBridge Submission Repository. This is because the existence of secondary applications in grouped submissions from other applications can only be identified with a complete pool scan. For the other eValidator appliances (desktop client, eValidator webAccess, Job Management), please note that the rule will not consider grouped submission scenarios.</p> <p>EVA-4497: Please make sure not to use OIDs for sponsor-defined code-systems that conflict with OIDs for pre-defined OIDs from ICH or regional authorities. Otherwise, the validation might result in multiple errors.</p> |



| Validation Impact | Description |
|-------------------|--|
| | <p>EVA-4812: This is a cosmetic correction only. It does not affect the actual validation results. PQ update should not be necessary.</p> <p>EVA-4575: This does not affect the validation results. PQ update should not be necessary.</p> <p>EVA-4336: Verify that US-eCTD4-038 reports an error when application.id.item@root is empty.</p> <p>EVA-4523: Verify that the output for US-eCTD4-555 always shows the affected Study ID, section number, and keyword code/codeSystem values.</p> <p>EVA-4521: Verify that US-eCTD4-536 does not report any findings for annotated CRFs and documents in 1.14 and 1.15. Please note that annotated CRFs will be identified through the file name: acrf.pdf or blankcrf.pdf.</p> <p>EVA-4498: The error was caused by a profile change in eValidator release 23.1 (EVA-4344).</p> |



4.1.12 US CDRH eCopy

| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|--|
| EVA-4572 | Minor | Feature | US FDA CDRH eCopy When publishing CDRH eCopy with docuBridge, the correct profile will now automatically be selected for validation. |

| Change Impact | Description |
|---------------------|--|
| Profiles | <ul style="list-style-type: none"> US FDA CDRH eCopy US FDA CDRH eCopy, EXTENDED |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|---|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-4572: Please verify that the eCopy profile will automatically be used when validation is triggered from docuBridge publishing. |



4.1.13 Expired Profiles

| Ticket Number | Priority | Type | Description |
|---------------|----------|------|---|
| EVA-4869 | Minor | Bug | The extended profiles for AU Nees 1.0 , AU Nees 3.0 and AU eCTD 3.0 from the expired profiles folder were not displayed as extended profiles in eValidator Desktop Client, eValidator webAccess, and LORENZ Job Management. This issue has been resolved. |

| Change Impact | Description |
|---------------------|----------------------------|
| Profiles | See profiles listed above. |
| Configuration Files | Changed |
| Program Code | No changes |

| Validation Impact | Description |
|-------------------|---|
| IQ | n/a |
| OQ | n/a |
| PQ | EVA-4869: Customers who are still using those expired profiles should verify that the profile titles are now correctly displayed in the eValidator applications. |



4.2 Reports and Style Sheets

| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|---|
| EVA-4620 | Major | Feature | <p>HTML and PDF Reports</p> <p>It is now possible to embed subreports in the main report. This option can be configured either via the new configPanel setting Embed subreports in report or the options menu in the eV Desktop Client. If this option is enabled, subreports will be embedded in the reports, otherwise they will be generated separately.</p> <p>With the feature enabled, all findings that previously appeared in the subreports will now be included in the main validation report using collapsible sections. In general, collapsible sections will be used for all rules that have more than 100 findings reported.</p> <p>In cases where the old stylesheet is used or the used profile does not support the embedding, all subreports will continue to be generated separately, irrespective of the setting.</p> <p>For further information, refer to the LORENZ eValidator Administrator and User Guides.</p> <p>Important: Decommissioning of Old Style Reports</p> <p>Note that with the next release, version 24.1, old-style reports will be decommissioned. This means that all reports will use the new stylesheet, subreport embedding will stay an optional feature.</p> |
| EVA-4741 | Major | Feature | <p>HTML and PDF Reports</p> <p>When validating through eValidator webAccess or LORENZ Job Management, the configured primary user time zone will be used for the Date/time of execution (local time) listed in the validation report.</p> |
| EVA-4619 | Major | Feature | <p>All active validation profiles have now been enabled to store validation results in the database. Please note that this also requires to activate the configPanel setting Save job results in database. This applies to validations executed through one of the following:</p> <ul style="list-style-type: none"> - eValidator webAccess - LORENZ Job Management - docuBridge Publishing - docuBridge Submission Repository <p>Results from validations executed in the eValidator desktop client will not be saved in the database.</p> <p>Expired and preflight profiles are exempt from storing results in the database.</p> |



| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|---|
| | | | Refer to the LORENZ eValidator Administrator Guide for further information. |
| EVA-4585 | Major | Feature | Validations triggered from eValidator webAccess will now always create a date/time folder for reports. The configPanel setting Create Date/Time folder for reports is ignored for validations triggered from eValidator webAccess. |
| EVA-4736 | Minor | Feature | HTML and PDF Reports The Additional or General Information section in job reports will now show the Job ID for validation jobs that have been executed via the LORENZ Job Management or eValidator webAccess. |
| EVA-4759 | Major | Bug | With validation results stored in the database using eValidator 23.1, some performance issues were observed when the validations had many findings. This has now been resolved. |
| EVA-4569 | Minor | Feature | HTML and PDF Reports In the sub-report table columns, page numbers will now show without leading zeros. Findings for the same document will still be sorted (natural order) by page numbers. The change does not apply to the legacy stylesheets (old format). |
| EVA-4571 | Minor | Feature | HTML Reports The eValidator logo displayed in validation reports is now embedded directly into the report and no longer referenced using a separate png file from the report folder. |
| EVA-4767 | Minor | Bug | If a sub-report was not referencing a sequence number, the sequence field would show n/a in the additional information section. This issue has been resolved now. If no sequence number is available, this field will not be shown. |

| Change Impact | Description |
|---------------------|-------------|
| Profiles | All |
| Configuration Files | Changed |
| Program Code | Changed |



| Validation Impact | Description |
|-------------------|---|
| OQ/PQ | <p>EVA-4620: If you plan to use the new embedding feature, please adjust your PQ documentation to reflect the configuration change and the new report structure.</p> <p>EVA-4741: If your OQ/PQ documentation refers to the timestamps listed in the job reports (in the General Information section and in the report header), please update the documentation accordingly: The timestamp time zone is now the user's time zone and no longer the server time zone. The additional UTC timestamp values are not affected by this change.</p> <p>EVA-4619: Additionally storing results in the database will not have any impact on the results written in the report files. Currently, there are no appliances to retrieve or use the validation data from the database. In future releases, dashboard gadgets and/or profiles to evaluate the statistics will be made available.</p> <p>EVA-4585: The actual validation results are not affected. No PQ update should be necessary.</p> <p>EVA-4736: This change improves the traceability of job reports. You can now directly see in the report which job has generated it. If the additional job ID information is relevant for you, please update your IQ accordingly.</p> <p>EVA-4759: In the previous release, only the US eCTD profile supported storing results in the database (when the corresponding configuration setting was activated in LORENZ configPanel). Customers who already used this feature and want to keep using should verify that the performance issues with larger validation results have been resolved.</p> <p>EVA-4569: This is a cosmetic change only. The actual validation results are not affected. No PQ update should be necessary.</p> <p>EVA-4571: The actual validation results are not affected. No PQ update should be necessary.</p> <p>EVA-4767: The actual validation results are not affected. No PQ update should be necessary.</p> |



4.3 LORENZ Job Management

| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|---|
| EVA-4559 | Not set | Feature | <p>A new profile to purge results from the validation database is now available in LORENZ Job Management. This profile can be used to remove old validation results from the database. Reports stored in the file system will not be removed using this profile. Within the profile, it is possible to select a time frame for the results that shall be removed, to specify certain applications and sequences and to specify if webAccess validation results should also be cleaned up.</p> <p>For further information, refer to the LORENZ eValidator Administrator Guide.</p> |

| Validation Impact | Description |
|-------------------|--|
| IQ/OQ/PQ | <p>EVA-4559:</p> <p>If you plan to store validation results in the database, please update your OQ/PQ documentation by adding the necessary steps to assign permission for this profile and the procedure to execute it (e.g., in a recurring manner, through job scheduling).</p> |



4.4 Setup and System Configuration

| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|--|
| EVA-4424 | Major | Feature | During installation of the LORENZ eValidator Server Setup it is now possible to deselect the eValidator webAccess feature in the installation dialog. |
| EVA-4545 | Minor | Feature | <p>Previously, the setting prefer_extended_profiles could only be changed in the eValidator system.config file using a text editor. It can now also be changed using LORENZ configPanel. When enabled, the extended version of validation profiles will be used in cases where the auto detect mechanism is used to determine the profile to execute.</p> <p>Refer to the LORENZ eValidator Administrator Guide and the LORENZ eValidator User Guide for further information.</p> |
| EVA-4465 | Major | Feature | For eValidator Server installations the database schema is mandatory now. The configPanel SubmissionValidationServices validation step will now check for the correct database schema. The check will fail if no or an incorrect database schema is present. |
| EVA-4524 | Major | Bug | <p>Missing eValidator in LORENZ configPanel</p> <p>When LORENZ Foundation 23.1 was installed in a location other than the default location (C:\Program Files (x86)\Lorenz Life Sciences\Foundation), the option to configure eValidator in the LORENZ configPanel was missing. This has now been resolved.</p> <p>This update was already available with the release 23.1.1</p> |
| EVA-4517 | Major | Bug | <p>Non-functional Setup Repair</p> <p>The Repair feature in the eValidator setup did not work as expected. After a Repair, sometimes no validation profiles were listed in LORENZ Job Management anymore or validations could not be executed. This has now been resolved.</p> <p>This update was already available with the release 23.1.1</p> |
| EVA-4519 | Major | Bug | <p>Database Migration Tool Issue</p> <p>When importing job records from eValidator 22.2 or older versions, the tool preserved the “executing” status for jobs found in the old database. The tool will now set the status to “aborted” for those</p> |



| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|--|
| | | | <p>jobs. The “executing” status was not correct (because the jobs were not actually executing anymore) and the user could not abort those jobs in LORENZ Job Management.</p> <p>This update was already available with the release 23.1.1.</p> |
| EVA-4825 | Major | Bug | The PowerShell script that was previously included in the eValidator setup to configure extension servers has been removed. This script should no longer be used, as the extension servers are now being configured via LORENZ Foundation. |
| EVA-4556 | Major | Feature | When upgrading to the eValidator 23.2 release, make sure to also upgrade the Foundation database schema to version 23.2. This is required to store validation results in the database. |

| Change Impact | Description |
|---------------------|-------------|
| Profiles | All |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|---|
| IQ/OQ | <p>EVA-4424: Please update your IQ documentation accordingly.</p> <p>EVA-4545: Please update your IQ documentation accordingly.</p> <p>EVA-4465: Please update your IQ documentation accordingly.</p> <p>EVA-4524: Customers who have LORENZ Foundation 23.2 or LORENZ eValidator 23.2 installed in a custom location other than the standard location: Please verify that after installing eValidator 23.2, the LORENZ configPanel has the eValidator in its configuration tree on the left. For this, the eValidator plugin file has been</p> |



| Validation Impact | Description |
|-------------------|--|
| | <p>installed in the subfolder “configPanel\plugins” of the LORENZ Foundation installation folder.</p> <p>EVA-4517: Customers who want to verify that the Repair function is now working properly should add the corresponding steps to the validation scripts. When executing Repair on a 23.1.1 or 23.2 installation, it should now result in a fully operable eValidator system. Normally, the Repair function is only needed when an existing installation got corrupted (e.g., when files were deleted accidentally).</p> <p>EVA-4519: Customers who want to migrate job records from a previous 22.2 or earlier version can add the corresponding steps to the validation scripts (please refer to the eValidator Administrator Guide for details). The issue mainly applies to job records from jobs that had not been aborted or terminated in the previous installation (e.g., Watchdog jobs). Those jobs kept the status “executing” in the job database of the previous installation. Normally, the is not the case with eValidator job records. It is very unlikely that the database of the previous version contained any jobs with status “executing” after upgrading the software to 23.2.</p> <p>EVA-4825: IQ update should not be necessary.</p> <p>EVA-4556: Please update your IQ by including the database schema update step.</p> |



4.5 eValidator webAccess (Submission Validation)

| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|--|
| EVA-4751 | Minor | Feature | <p>The Validation Properties that were previously available through the info icon in the upper right corner of the profile navigation tree pane have now been moved to toolbar and context menu of the currently selected validation. The context menu can be accessed through right clicking a single selected validation.</p> <p>For further information refer to the LORENZ eValidator webAccess User Guide.</p> |
| EVA-4740 | Minor | Feature | <p>For a more user-friendly selection of multiple validations in the validations pane, checkboxes have been added to the items. Click the checkbox displayed in the table header to select or unselect all validations displayed in the validations pane.</p> <p>For further information, refer to the LORENZ eValidator webAccess User Guide.</p> |
| EVA-4764 | Minor | Feature | <p>The Validate Grouped Submission option in context menu and toolbar is now only available when the primary application sequence (the group's top-level node) of a grouped submission has been selected.</p> |
| EVA-4753 | Major | Feature | <p>The eValidator webAccess startup speed has been improved. In tests, the startup time decreased from 25 to 5 seconds for a user with 900 stored validations.</p> |
| EVA-4513 | Major | Feature | <p>The eValidator webAccess application is no longer dependent on IIS being available on the system. webAccess is now served via the LORENZ Foundation WebContentServices.</p> <p>For further information, refer to the LORENZ Foundation Administrator Guide.</p> |
| EVA-4901 | Critical | Bug | <p>Validation profile files were kept locked when they had been opened via eValidator webAccess. This caused errors when the users tried to install a regulatory update package. The issue has now been resolved.</p> |
| EVA-4796 | Marginal | Bug | <p>An issue that could cause report types (html, pdf, zip) to be listed in an unsorted manner in the report pane table columns has been resolved.</p> |



| Ticket Number | Priority | Type | Description |
|---------------|----------|------|---|
| EVA-4752 | Minor | Bug | An issue with the pool name in the properties dialog not being displayed correctly has been resolved. Furthermore, to improve usability, the cancel button in view mode has been renamed to Close and an icon has been added to the Save button in edit mode. |

| Change Impact | Description |
|---------------------|-------------|
| Profiles | n/a |
| Configuration Files | Not changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|---|
| IQ/OQ/PQ | <p>EVA-4751: Please adjust your PQ documentation to reflect the change in the user interface.</p> <p>EVA-4740: Please adjust your PQ documentation to reflect the change in the user interface.</p> <p>EVA-4764: Please adjust your PQ documentation to reflect the change in the user interface.</p> <p>EVA-4753: No PQ update should be necessary.</p> <p>EVA-4513: The corresponding IQ update should be done in the IQ documentation for LORENZ Foundation.</p> <p>EVA-4901: Customers who encountered issues installing a Regulatory Update Package (RUP) due to locked profiles should verify with the next RUP that the issue no longer occurs.</p> <p>EVA-4796: No PQ update should be necessary.</p> <p>EVA-4752: Please adjust your PQ documentation to reflect the change in the user interface.</p> |



4.6 Dashboard Gadgets

| Ticket Number | Priority | Type | Description |
|---------------|----------|------|---|
| EVA-4798 | Major | Bug | <p>Two issues with validation gadgets have been resolved:</p> <ul style="list-style-type: none"> The Validation Job Results gadget did not display any results. This has now been resolved, validation results can be displayed using the gadget. The Validation Completed Jobs gadget did now show jobs that completed execution without any findings. When configured to also show jobs with completion status passed, the gadget will now display those jobs. |

| Change Impact | Description |
|---------------------|-------------|
| Profiles | n/a |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|---|
| IQ/OQ/PQ | <p>EVA-4798:</p> <p>Customers who wanted to use the dashboard gadgets should verify in the PQ that the gadgets are now working as expected.</p> |



4.7 REST API & Scripting

| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|--|
| EVA-4258 | Not set | Feature | For validations that have been configured to store results in the database it is now possible to request the reports through a corresponding Job Management API endpoint. For further information, refer to the Job Management API Swagger page. |
| EVA-4548 | Major | Bug | <p>In the PortalServices or JobManagementServices log files, error messages were recorded related to eValidator, directly after a user logged into any LORENZ web application. This has now been resolved. The issue occurred with the docuBridge built-in license only but not with eValidator FIVE licenses.</p> <p>This update was already available with the regulatory update package 1.11.2.</p> |

| Change Impact | Description |
|---------------------|-------------|
| Profiles | n/a |
| Configuration Files | Changed |
| Program Code | Changed |

| Validation Impact | Description |
|-------------------|---|
| IQ/OQ/PQ | <p>EVA-4258: The feature has been made available for testing purposes. In a future version, generating reports directly from the results stored in the database will be a configurable option.</p> <p>EVA-4548: This only applies to unsolicited log file output. Validation results were never affected. Therefore, PQ update should not be necessary.</p> |



4.8 Miscellaneous

| Ticket Number | Priority | Type | Description |
|---------------|----------|------|--|
| EVA-4779 | Critical | Bug | The eValidator crashed when the submission with the highest sequence number in an application with more than about 5200 sequences in the application folder was being validated. This issue has been resolved now. |
| EVA-4417 | Major | Bug | <p>The following configuration files and profiles have been modified to resolve potential issues with non-unique localization IDs. The changes do not affect the business logic or validation results.</p> <ul style="list-style-type: none"> • Profiles/Expired/Profile_CH_1-1.xml • Profiles/Profile_ConfigurationUpdate.xml • Profiles/Profile_GCC_VNeeS_Immu_4-1.xml • Profiles/Profile_GCC_VNeeS_MRL_4-1.xml • Profiles/Profile_GCC_VNeeS_Pharma_4-1.xml • Modified Profiles/Profile_PDF_QC_USFDA_Multiple.xml • Profiles/Profile_PDF_QC_USFDA_Single.xml • Profiles/Profile_US_eCTD4.xml • Profiles/Profile_ZA_NeeS_1-0_Extended.xml • Resources/LORENZ.Automator.Profile_ConfigurationUpdate.en-US.resources.resx • Resources/LORENZ.Automator.Profile_ConfigurationUpdate.fr-FR.resources.resx • Resources/LORENZ.Automator.Profile_ConfigurationUpdate.zh-CN.resources.resx |
| EVA-4880 | Major | Bug | For validations triggered from docuBridge publishing jobs: If the setting prefer extended profiles has been activated in the LORENZ configPanel, but the extended profile for the corresponding region has not been licensed, the validation will now use the standard profile instead. Previously the validation failed in such cases. |

| Change Impact | Description |
|---------------------|-------------|
| Profiles | n/a |
| Configuration Files | Changed |
| Program Code | Changed |



| Validation Impact | Description |
|-------------------|--|
| IQ/OQ/PQ | <p>EVA-4779: So far, the issue happened with one specific US eCTD application only. If you encountered the issue in any of the previous releases, please re-validate to verify that the issue is now resolved.</p> <p>EVA-4417: No PQ updates should be necessary.</p> <p>EVA-4880: Customers who have been using the Prefer extended profiles setting for validation triggered by docuBridge publishing should update their PQ script to consider that fallback to the standard profile when the extended profile is not licensed.</p> |



4.9 Known Issues

| Ticket Number | Priority | Type | Description |
|---------------|----------|---------|---|
| EVA-4786 | Minor | Feature | ECOWAS eCTD and eSub localization The Portuguese and French translations for validation report for ECOWAS eCTD and eSubmission validations are not yet available. Validation reports will be displayed in English. This will be corrected in future update packages. |
| EVA-4883 | Marginal | Bug | Date Filters in eValidator webAccess and LORENZ Job Management A known issue was identified where date filters in table headers do not correctly indicate the current day if the system time and primary time zone of the user differ by a day. This issue only affects the displayed highlighting but does not affect the functionality. |

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Internet: www.lorenz.cc | E-Mail: www.lorenz.cc/email

LORENZ Archiv-Systeme GmbH

Eschborner Landstrasse 75
60489 Frankfurt/Main
GERMANY

Tel +49 69 78 991-901
Fax +49 69 78 991-129

LORENZ International LLC

1515 Market Street, Suite 1200
Philadelphia, PA 19102
USA

Tel +1 866 9567 369
+1 866 9LORENZ
Fax +1 866 2956 967

LORENZ Life Sciences Ltd.

No. 1 Farnham Road
Guildford, Surrey GU2 4RG
UNITED KINGDOM

Tel +44 14 83 903 861
Fax +44 20 76 812 676

LORENZ Life Sciences India Pvt Ltd.

Olympia Tech Park, Level -2, Altius
No: 01, Sidco Industrial Estate
Ekkatuthangal, Guindy
Chennai-600 032
INDIA

Tel +91 44 42 994 219
Fax +91 44 42 994 310

LORENZ Polska

APC Instytut Sp. z o.o.
Al. Jerozolimskie 146 c
Warsaw 02-305
POLAND

Tel +48 22 6686 823
Fax +48 22 6689 981

Digital Media System Co., Ltd.

Tsukiji No. 1
Nagaoka Building 2-3-4
Tsukiji, Chuo-ku, Tokyo 104 - 0045
JAPAN

Tel +81-3-5550 5595
Fax +81-3-5550 5596