



TRS Viewer 4.0.0300

Release Notes

Issue Date: 21-Jun-2019

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Revision History

Version	Date	Revised By	Comments
1.0	29-March-2019	Asma Saiyed	<ul style="list-style-type: none">Initial Release for TRS Viewer 4.0.0300 – Swissmedics CH (1.4), Jordan JO (1.0.2) & Veeva Vault Integration
2.0	21-Jun-2019	Sadia Ahmed	<ul style="list-style-type: none">TRS Viewer 4.0.0300 – China (CN) v1.0 release<ul style="list-style-type: none">❖ Section 3: “What’s New in this Release” is updated to include China, Multi Language Support and eCTDExpress Multi-language Integration❖ Section 4: “Documentation” is updated to reflect changes in documents for China (CN) v1.0❖ Section 6: “Limitations” is updated to include VWR-1516 & VWR-1521 limitation for CN 1.0❖ Section 7: “Resolved in This Release” is updated to include new issues (VWR-1423 to VWR-1523)❖ Section 8: “Identified in this Release” is updated to remove VWR-1474 & VWR-1473 which are resolved in this release.❖ Section 9: “Identified in Previous Release” is updated to include new issues (VWR-1414 & VWR-1424)





1. Content

Viewer is a web-based solution for viewing dossiers from archive locations, such as a file system, Documentum, Veeva, FirstDoc and SharePoint. When configured with eCTDExpress, Viewer can additionally view in-progress submissions.

When hosted on your network, Viewer can utilize Windows Active Directory to allow for active directory user to login with their credentials. Additionally, from within Viewer you will have the ability to access to dossiers from other locations via mapped credentials, such as a file system.

Viewer can also be integrated with Tracker and FirstDoc. Viewer provides integration interface to allow for the ability to launch a view of Applications and Submissions from within external systems. Viewer provides several options for locating specific dossiers, identifying your favorite dossiers, and viewing eCTDs with cumulative, single or related sequences. In addition to viewing eCTDs, you can also view NeeS and other non-eCTD dossiers.

The content of this release notes identifies core functionalities of TRS Viewer application.

2. Minimum System Requirements

The minimum system requirements for running TRS Viewer 4.0.0300 are recorded in the TRS Viewer 4.0.0300 System Requirements Definition. Please reference “Software Requirements” section of the document for the versions of software components with which TRS Viewer 4.0.0300 was tested.

3. What's New in this Release

This section highlights new features and functional enhancements released with the TRS Viewer 4.0.0300.

- **China (CN) M1 Specification released on March 01, 2019 (Schema ver. 1.0):** To allow users to comply with recent adoption of the eCTD in China region, Viewer 4.0.0300 release supports viewing of CN M1 eCTDs using draft guidance released on March 01, 2019. The following specific functions for CN region are introduced as part of this release:
 - ❖ Ability to register and cache China (CN) v1.0 eCTD dossier.
 - ❖ Ability to display China (CN) v1.0 eCTD submission both archived and in-progress application/dossier.
 - ❖ Support different Views (cumulative, current, related sequence view etc.), search and filter capabilities for China eCTDs.

Note: When the eCTD guidance is finalized by the CN agency, DXC team will evaluate the changes and inform clients via TRS Online User Community (OLC) if updates (i.e. hotfix/patch) are required for Viewer.

- **Multi-language (English-Chinese) Support:**





- ❖ Provide ability to switch languages (English or Chinese) on Meta Data & Outline tree view.
- ❖ The feature is only effective to view M1-M5 of CN v1.0 dossiers/submissions. And the UI of Viewer application remains in English language.
- **eCTDXPath Multi-language Integration:**
 - ❖ Provide base Viewer installer package compatible with eCTDXPath 4.0.0300 Multi-Language pack.
- **Veeva Vault Integration:** Viewer is now integrated with Veeva Vault, supports the ability to recognize and display documents, submissions in viewer
- **JO M1 Specification version 1.0.2 (DTD ver. 1.0.2):** Support ability to recognize and display Jordan (JO) Region DTD v1.0.2 for both archived and in-progress application/dossier.
- **CH M1 Specification version 1.4 (DTD ver. 1.4):** Support ability to recognize and display Swiss (CH) Region DTD v1.4 for both archived and in-progress application/dossier.





4. Documentation

The TRS Viewer 4.0.0300 documentation includes the following items:

Deliverable Name	Version
TRS Viewer 4.0.0300 System Requirements Definition	2.0
TRS Viewer 4.0.0300 Configuration Requirements Specification	3.0
TRS Viewer 4.0.0300 Release Notes	2.0
TRS Viewer 4.0.0300 Software Certification Summary	3.0
TRS Viewer 4.0.0300 Installation Guide	3.0
TRS Viewer 4.0.0300 Administration Guide	2.0
TRS Viewer 4.0.0300 Training Guide	2.0
TRS Viewer 4.0.0300 User Manual	2.0
TRS Viewer 4.0.0300 What's New QRC	3.0

5. Capabilities

For detailed capability information, please refer to the TRS Viewer 4.0.0300 User Manual.

6. Limitations

Bug #	Description	Software Module	Additional Notes
VWR-1469	Sequence & Module level security/restriction feature on Folder Structure View does not work for Veeva.	Veeva	The features are working normally with Outline Tree View on Viewer. The reason they don't work with Folder Structure View because Viewer shows the same way Veeva DMS is showing application and Veeva does not show standard folder structure as Application -> Submission -> Module level. They show directly Application -> Modules which are renamed.





VWR-1516	Unable to open large dossier (200+ sequences) on Veeva DMS. Discovery Veeva Agent Cannot register larger dossier from Veeva Repository. This issue occurs because of response size more than size of maxJsonLength property during serialization or deserialization.	Veeva	The issue is applicable for TRS Publishing 4.0.0300 and the update is required for 'CSC.TRS.WCF.DMS.Implementation.VeevaVault.dll' in TRS Publishing Veeva DMS Service.
VWR-1521	For CN 1.0 support, the agency provided schema does not include code and code-version attributes for application-type, product-type, regulatory-activity-type and sequence-type fields as defined in the specification and the corresponding attribute files (TRS-4105). Therefore, Viewer is not able to archive CN v1.0 submission to Veeva directly from eCTDExpress.	Dossier View – eCTD	The Viewer functionalities is working as expected with an archived CN v1.0 submission where regional xml of the submission was manually modified to pass xml validation and the checksum for dtd/stylesheet is adjusted accordingly.





7. Resolved in This Release

The following issues were resolved in this release.

Bug #	Description	Software Module	Additional Notes
VWR-1419	Annotation Report for Non-eCTD Dossier is not displayed on Outline Tree, the error message displays indicating Index was outside the bounds of the array.	Reports - Annotations	
VWR-1423	Performance improvement when opening large dossiers (200 & 700 sequences)	Viewer Core Service	Related to case DXC155109
VWR-1426	Issue with Filter in User Group Management tab and load access tab of "Biologics Viewer" group	Administration - User Group Management	Related to case DXC153722
VWR-1473 VWR-1492	Hyperlink and Bookmark (external link) is not working for "Submission Archived" on Veeva eCTD Application.	Veeva	
VWR-1474	US3.3 - Cannot open document under all M1 nodes in non-hierarchy structure dossier. When the number of users and associated privileges are big. The time to process the request of query user access privileges exceed the default PostBackTimeout of the <telerik:RadScriptManager> control on the User Management page. That causes the list of user privileges cannot to be retrieved by the User Management web page	Dossier View - eCTD	
VWR-1477	The icon for documents of primary submission is not displayed. Updated code to get correct Grouped Submission Type of Submission	Dossier View – eCTD	
VWR-1478	US3.3 Group Submission - Cannot open document which belongs to non-primary submission in non-hierarchy structure dossier	Dossier View - eCTD	
VWR-1484	Cannot Open Repository with file uploaded into "Submissions Archive\Structure" or "Submissions Archive\Content" (without binder) on Veeva Vault	Veeva	
VWR-1491	Failed to open Outline page of dossier with large number of sequences. Viewer web site has to pass the whole data of the dossier which include submissions to Web Service API. If the number of submissions is large and with large number of leaf nodes in backbone files of submission, the object data of dossier is large then when it is serialized to messages to transfer via HTTP, the http message size exceed the default message size configuration of Web Service server. It causes the exception return to Viewer web outline page.	Dossier View – eCTD	





VWR-1517	<p>The app service log announces error logs after Viewer Agent scans dossiers of EU/JO/US region.</p> <ul style="list-style-type: none">Agency Name metadata is not cached successfully.The Agent Name metadata will be displayed its code only when showing at Regional Information Tab. <p>The submission of US application is removed by Agent Caching when it caches the large application.</p>	Agents
VWR-1519	<p>Some dossiers/sequences are not displayed on outline tree because of deadlocked issue in Job Service when deploying multiple DMS services on multiple agent servers. Deadlock is created because of conflict transactions when multiple DMS services execute query insert submissions at the time.</p>	Job Service - Caching Agent
VWR-1523	<p>Config “<add key=“DossierViewer.ShowUnCompiled” value=“false” />” is removed from web.config file as it is no longer used by Viewer.</p>	Viewer Web

8. Identified in this Release

None.

9. Identified in Previous Release

Bug #	Description	Software Module	Additional Notes
VWR-130	When we have Excipient as [NULL] inside eCTDXPath, the order of folders from 3.2.P.4.1 to 3.2.P.4.6 under 3.2.P.4 section on Viewer is not same as in eCTDXPath.	Dossier Review	
VWR-150	The paging option on Correspondence Settings is not shown.	Administration	
VWR-165	Document Type should be disabled when the selected docbase is not FirstDoc.	Administration	
VWR-169	System should display error message when user inputs special characters in Repository Settings or User Management.	Administration	
VWR-186	In-progress dossier: Mismatch between Viewer and eCTDXPath in TOC mode.	Dossier Review	





Bug #	Description	Software Module	Additional Notes
VWR-214	The webserver configurations or settings in the database are not cleared, when the same database connection is used for a different webserver (swapping Webservers) machine.	Database	
VWR-219	User cannot open documents for in-progress dossiers that are compiled to Output location at FirstDoc, SharePoint and Documentum where path exceeds 256 characters.	Dossier Review	
VWR-222	User cannot move to the second document by clicking next icon on the top of document.	Dossier Review	
VWR-318	In some cases, Viewers displays folder node although its document no longer existed in Current View.	Dossier Review	
VWR-339	Group Submission: Lifecycle box is not displayed when non-primary submission starts with Append, Replace or Delete Lifecycle.	Dossier Review	
VWR-652	View Version option is enabled in outline tree context menu for STFs.	Dossier Review	
VWR-707	The text is not highlighted when searching for both value and name of metadata folder nodes (ICH and Regional).	Dossier List	
VWR-729	For SharePoint 2013, Viewer is not able to get information from SharePoint Subsite.	Agents	
VWR-797	Hyperlink/ bookmark navigation does not work in FirstDoc/Veeva when the dossier is archived with the different name.	PDF Navigation - Adobe Plugin	
VWR-922	Viewer does not authenticate user mapping containing asterisk (*).	Administration	





Bug #	Description	Software Module	Additional Notes
VWR-962	Duplicate records are displayed in Audit Trail Report in Edge browser (uncheck "Open PDF using JavaScript").	Audit Trail	<p>This is the limitation from Microsoft: https://developer.microsoft.com/en-us/microsoft-edge/platform/issues/6734131/</p> <p>Note: This is Microsoft issue where it downloads PDF-files twice. This will happen only when user opens PDF file in its browser. This issue will not happen if user opens the PDF using JavaScript approach (check the checkbox "Open PDF using JavaScript" in User Preferences.)</p>
VWR-1176	Lifecycle boxes are not displayed correctly when viewing application with ICH 3.0 and STF 2.0.	Miscellaneous	
VWR-1224	Save button is disabled when the owner delete/clear all criteria and re-add those criteria.	Advanced Search	<p>It can work-around to enable Save button by three ways:</p> <ol style="list-style-type: none">1. User can add a new row or add new search criteria by select dossier/metadata above grid before click on delete icon to delete old criteria.2. After delete/clear all criteria and add new criteria into grid, user can re-input search filter name in order to enable Save button.3. When user clear all search criteria, its same with add new a search filter.
VWR-1228	System does not show the error message in UI when the dossier includes invalid submission backbone files.	Miscellaneous	Workaround: Error message is captured in Log file





Bug #	Description	Software Module	Additional Notes
VWR-1236	Advance Search: For primary application when searching for 'application-number' of US 3.3 group submission does not show non-primary dossier.	Advanced Search	
VWR-1248	Viewer is displaying an empty folder with title "Submission Information" even when there are no leaves.	Dossier View - eCTD	
VWR-1254	Advance Search: Some value of 'language' metadata cannot be searched for In-progress dossier of EU dossiers.	Advanced Search, Quick Search	
VWR-1268	Administrator must define the domain name before creating a windows user.	Administration View	
VWR-1327	Login privileges should be granted by default, when Password Settings, Public Search Filter and Caching Job Export & Delete privileges are applied.	Administration - User Group Management	
VWR-1328	If total user license has been maxed out, system does not allow adding User to Group with 'All to Left' button.	Administration - User Group Management	
VWR-1331	Copy URL for folder explorer for eCTD dossier is not supported.	Dossier Review	
VWR-1333	Empty group can't be grant permission if maximum number of licenses is reached.	Administration - User Group Management	
VWR-1334	System is allowing to grant privileges for the users even licenses are exceeded, however system is restricting during login.	Administration - User Group Management	
VWR-1362	Copy URL pop-up does not have cancel or close button when PDFJS is turned off. The issue is only with IE browser.	Dossier View - eCTD	To work around, user can copy the link by selecting the URL from text box and Ctrl-C and close the dialog by clicking on the little Viewer icon to close.
VWR-1382	With JP submission, the original and copied document are opened on ONE tab for open document mode.	Dossier View - eCTD	
VWR-1394	JP submission: deleted lifecycle is not displayed in Single View for JP region	Dossier View - eCTD	Lifecycles are correctly displayed in cumulative view
VWR-1396	Having the reference document added under Novel Excipient node, the value of Novel Excipient folder is blank.	Dossier View - eCTD	





Bug #	Description	Software Module	Additional Notes
VWR-1411	Cross reference icon may not be displayed for the reference leafs where leaf's href and folder section are not in sync.	Dossier View - eCTD	
VWR-1414	eCTDCaching report is showing duplicate information when modify a sequence of Group Submission.	Job Service – Caching Service	
VWR-1418	Acrobat 2017 does not support some types of annotation	Annotation	User can successfully create annotation with Highlight, Text (Sticky Note), Caret (Insert Text), StrikeOut + Caret (Replace Text), Strike Out, FreeText (Text box), Polygon (Cloud), Polygon, PolyLine, Ink, Highlight (Comment on text), Underline
VWR-1424	Unable to view documents due to Windows folder/file length path being exceeded in cache directory.	Job Service – Caching Agent	Related to incident# DXC153857

10. Open Source Software Components

TRIS Viewer 4.0.0300 is delivered with Open Source Software (OSS) components developed and owned by third parties. OSS components may be used solely according to the terms and conditions of the specific licence under which the relevant OSS components are distributed, but, in all instances, are provided "AS IS" by such third parties and DXC. Warranties, if any, provided by DXC with respect to its proprietary software are not made by such third parties.

11. Problem Reporting

Issues regarding TRIS Viewer 4.0.0300 that originate from individuals outside of DXC should be directed to trssupport@dx.com

Please be sure to include the name of your project and the version of TRIS Viewer that you are currently running with (i.e. TRIS Viewer 4.0.0300).

