

OmniVIEW Next Generation

How-To Guide

Revision Sheet

Revision	Revised on Date	Content Updates
Rev-1	01/04/2019	Sprint 1 Topics: Introduction to OmniVIEW, First Time Login, Forgot Password, and Accessing Application
Rev - 2	01/28/2019	Validate Submission
Rev - 3	02/19/2019	Restructured and edited the complete file for font, spacing, format, grammar and spelling mistakes as per the provided inputs on old docs.

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What is OmniVIEW?

OmniVIEW is a cloud-based solution that allows you to view and validate the submissions in Electronic Common Technical Document (eCTD) format with XML support. It efficiently converts and manages the complex clinical/pre-clinical research data into different region-specific eCTD templates / submission formats. It also allows you to view the submissions in Life Cycle view and perform validations at any stage of the drug development. With little time in hand, OmniVIEW lets drug makers all around USA, Europe and Canada seamlessly plan and submit their region-wise eCTD submissions, leading to the faster drug approvals.

Each submission message consists of a sequence as per the common global standards. A collection of OmniVIEW eCTD file consists of one or more sequences. You can view a single sequence in a web browser. However, to view the collection of sequences, use OmniVIEW application.

Following is a sample directory structure:

- ctd-123456/0000/index.xml
- ctd-123456/0000/index-md5.txt
- ctd-123456/0000/m1
- ctd-123456/0000/m2
- ctd-123456/0000/m3
- ctd-123456/0000/m4
- ctd-123456/0000/m5
- ctd-123456/0000/util

The string ctd-123456/0000 is an example.

The Index File

Index.xml file acts as a backbone to the submission sequence number folder.

For example: ctd-123456/0000/index.xml

The index.xml file has two purposes as follows:

- Manage meta-data for the entire submission.
- Constitute a comprehensive table of contents and provide corresponding navigation aid.

How to Login for the First Time?

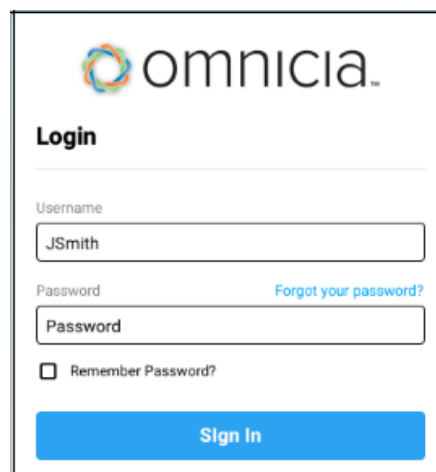
You can Login into OmniVIEW with the Username and Password provided by your administrator. After your administrator creates your profile, an email is sent to you with the login credentials. You can login to OmniVIEW using those credentials.

Note:

- If you do not have login credentials, please contact your company's administrator.
- You can create your new profile only when you are logging in for the first time.

Logging in the first time:

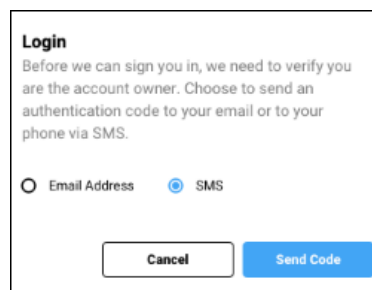
1. Open the email you have received from your administrator and click the link. The OmniVIEW Login page appears.



The image shows the OmniVIEW login page. At the top is the 'omnicia' logo. Below it is the heading 'Login'. There are two input fields: 'Username' with the text 'JSmith' and 'Password' with the text 'Password'. To the right of the password field is a link that says 'Forgot your password?'. Below the password field is a checkbox labeled 'Remember Password?'. At the bottom is a large blue button labeled 'Sign In'.

Figure 1: Login Page

2. In the 'Login' page, enter the **Username** and **Password** that you have received in the email.
3. Click **Sign In**.
The Authentication page appears.



The image shows the login verification page. It has the heading 'Login' and a message: 'Before we can sign you in, we need to verify you are the account owner. Choose to send an authentication code to your email or to your phone via SMS.' There are two radio buttons: 'Email Address' and 'SMS', with 'SMS' being selected. At the bottom are two buttons: 'Cancel' and 'Send Code'.

Figure 2: Login Verification

4. In the 'Authentication' page, select either **Email Address** or **SMS** to receive the authentication code.
5. Click **Send Code**.
6. In the 'Authentication Code' text box, enter the code that you have received.
7. Click **Login**.
The Create Your Profile page appears.

Create Your Profile

Complete the form below to create a profile. Fields with an * are mandatory.

Username and Password

Create a unique username and password. Passwords must be (password requirements go here)

Username*

Password*

Password Again*


User Details

First Name*

Last Name*


Email Address*

Phone Number*

 (123) 456-7890

Profile Picture

(Profile picture file size requirements go here)

 Drag & Drop or [Choose File](#)

Save & Submit

Cancel

Figure 3: Create Profile

8. In the 'Create Your Profile' page, verify if the information such as **Username**, **First Name**, **Last Name**, and **Email Address** are correct.
9. In the 'Profile Picture', click **Choose File** to upload your profile picture.
10. Click **Save & Submit**.
Your profile details get saved successfully and OmniVIEW Dashboard page appears.

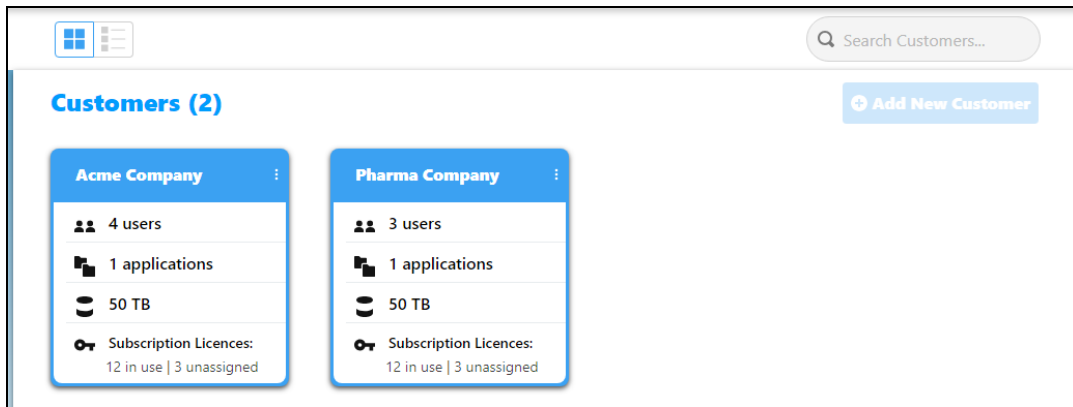


Figure 4: Dashboard

How to Login for the Subsequent Times?

You can login to OmniVIEW with the **User ID** and **Password** created by your administrator.

Note: If you do not have Login credentials, please contact your company's administrator.

Logging in the subsequent times:

1. Open the OmniVIEW **Login** page.

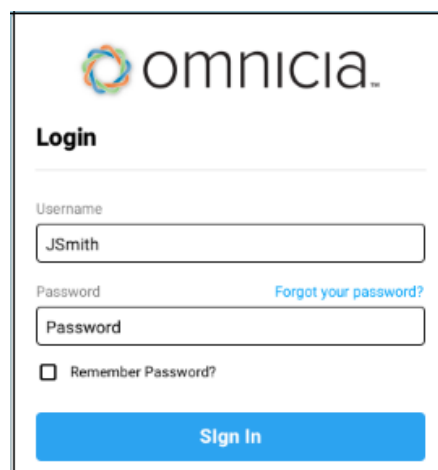
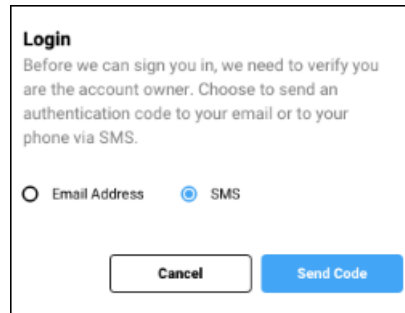


Figure 5: Login Page

2. In the 'Login' page, enter the **Username** and **Password**.
3. Click **Sign In**.
The Authentication page appears.



The image shows a 'Login' dialog box. It contains the text: 'Before we can sign you in, we need to verify you are the account owner. Choose to send an authentication code to your email or to your phone via SMS.' Below this text are two radio buttons: 'Email Address' (unselected) and 'SMS' (selected). At the bottom are two buttons: 'Cancel' and 'Send Code'.

Figure 6: Login Verification

4. In the 'Authentication' page, select either **Email Address** or **SMS** to receive the authentication code.
5. Click **Send Code**.
6. In the 'Authentication Code' text box, enter the code that you have received.
7. Click **Login**.
The OmniVIEW Dashboard page appears.

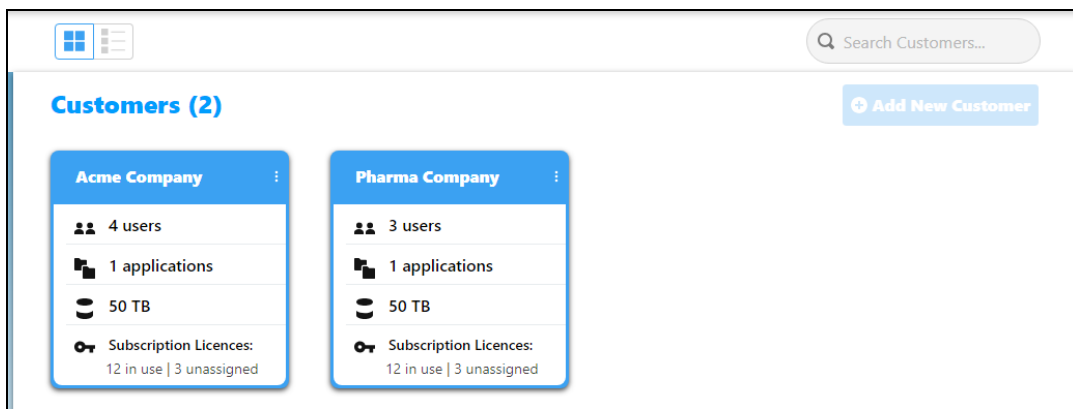


Figure 7: Dashboard

How to Retrieve a Forgotten Password?

You cannot retrieve your current password. However, you can set a new password.

Setting a new password:

1. On the 'Login' page, click **Forgot Your Password?** link.
The Forgot Password page appears.

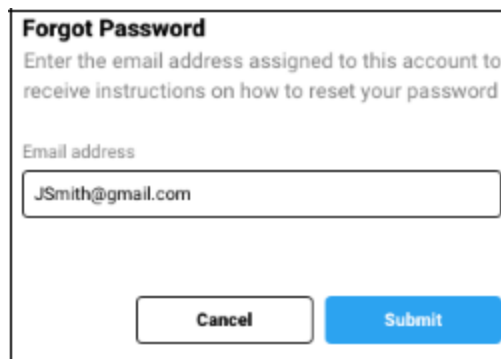
A screenshot of a web form titled "Forgot Password". Below the title is a subtitle: "Enter the email address assigned to this account to receive instructions on how to reset your password". There is a text input field labeled "Email address" containing the text "JSmith@gmail.com". At the bottom of the form are two buttons: "Cancel" and "Submit".

Figure 8: Forgot Password

2. In the 'Forgot Password' page, enter the **Email Address** to which you want to receive the instructions to reset your password.
The Authentication page appears.
3. In the 'Authentication' page, select either **Email Address** or **SMS** to receive the authentication code.
You will receive an authentication code.
4. In the 'Authentication' text box, enter the authentication code you have received.
The Create a New Password page appears.

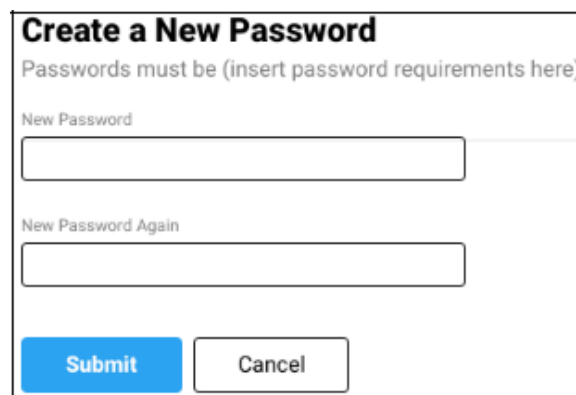
A screenshot of a web form titled "Create a New Password". Below the title is a subtitle: "Passwords must be (insert password requirements here)". There are two text input fields: the first is labeled "New Password" and the second is labeled "New Password Again". At the bottom of the form are two buttons: "Submit" and "Cancel".

Figure 9: Create New Password

5. In the 'Create a New Password' page, enter your **New Password**.
6. In the 'New Password Again' field, enter your **New Password Again**.

7. Click **Submit**.
Your password is changed successfully.

Dashboard

1. 'Login' into **OmniVIEW**.
The Dashboard page appears with the list of customers that you can access.

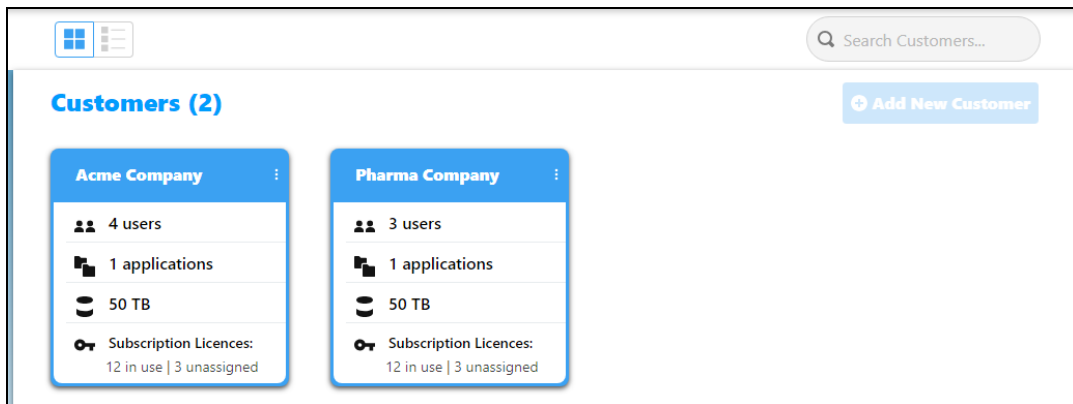


Figure 10: Dashboard

2. In the 'Dashboard' page, click the customer for which you want to view the **Applications**.
List of Applications available under the selected customer appears.

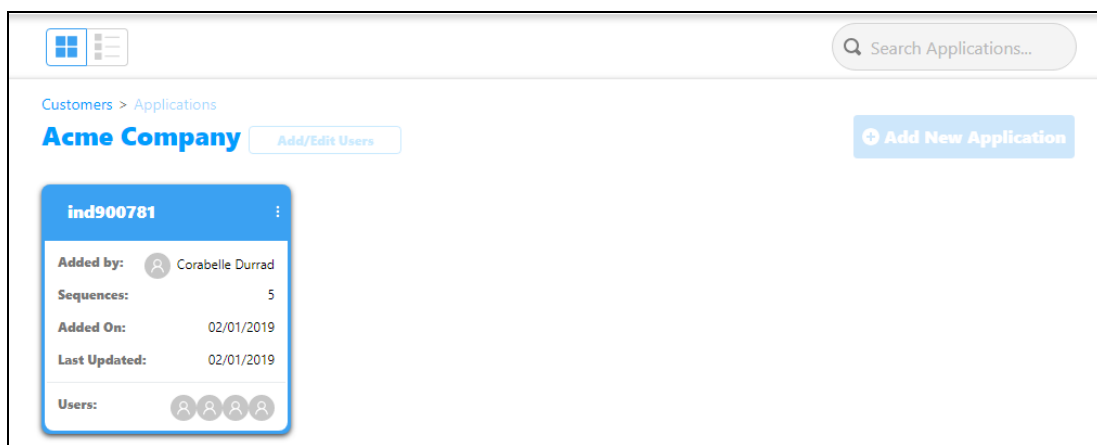


Figure 11: Application Page

3. Click the 'Application' for which you want to view the list of **Sequences**.
The list of Sequences appears.

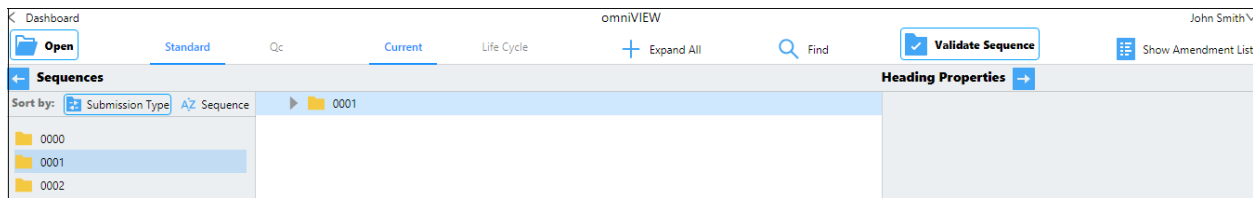


Figure 12: Sequences

- In the 'Sequences' pane, click ▼ arrow for the required node till you reach the file you are looking for as shown in the following screenshot.

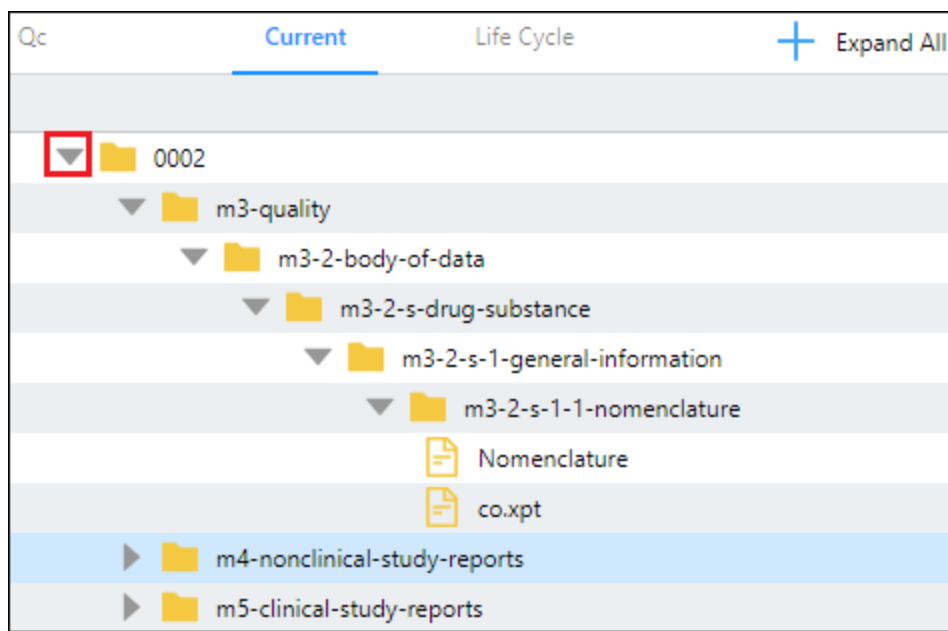


Figure 13: Submission File Structure

- Click a node or a file to view the properties in the **Heading** or **Document Properties** pane as shown in the following screenshot.

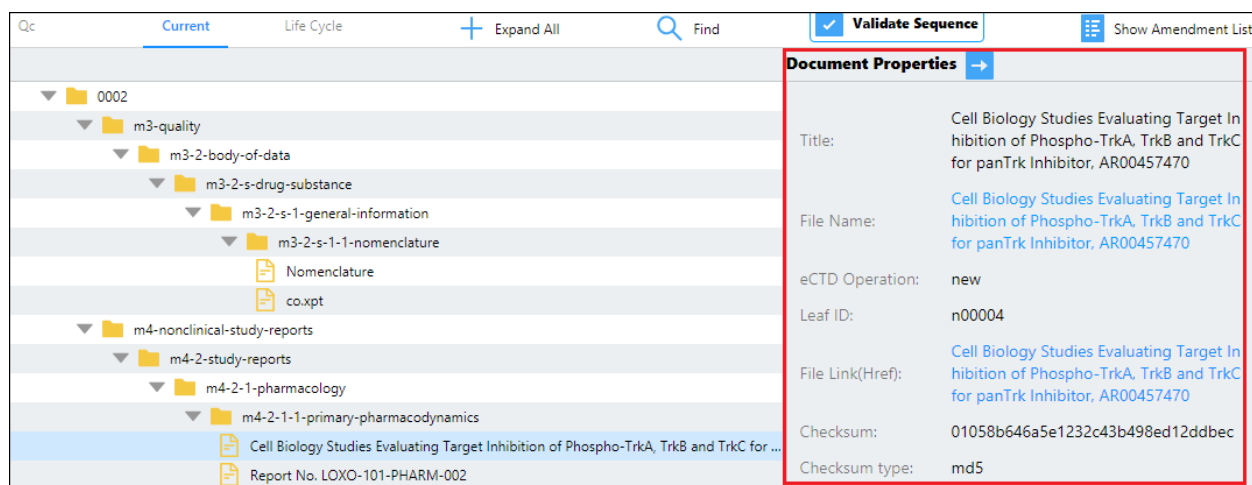


Figure 14: Properties Pane

In addition to the 'Current' view, you can view the application in **Life Cycle** view.

In the Current view, you can perform all the amendments as follows:

- Add a node or file
- Replace a node or file
- Append a node or file
- Delete a node or file

In the Life Cycle view, for a file or a node, you can view the list of amendments performed for a file or a node.

How to Access Applications (Submissions)?

You can access all the Applications related to a customer and perform tasks such as follows:

- Open sequences
- View amendment list
- Expand all the nodes at once
- Validate sequences and so forth

You can view the structure of a Sequence in the following modes:

- **Standard Mode**
- **QC Mode**

OmniVIEW supports the following display options in both **Standard** and **QC Mode**:

- **Current View**
- **Life Cycle View**

How to Validate a Sequence?

You can scan and validate a sequence according to your regional (CA, EU, and the US) validation criteria.

For each validation, details such as error number, description, and the following severity levels are displayed:

- **High:** This is a serious technical error which prevents the processing of the submission and requires a resubmission.
- **Medium:** This error might impact the reviewability of the submission which can be determined by further inspection.
- **Low:** This is a technical error which might or might not impact the reviewability or the integrity of the submission.

Note: For the latest version of the eCTD validation guidance documents, visit appropriate website.

Validating a sequence:

1. Log into OmniVIEW and access the required sequence.

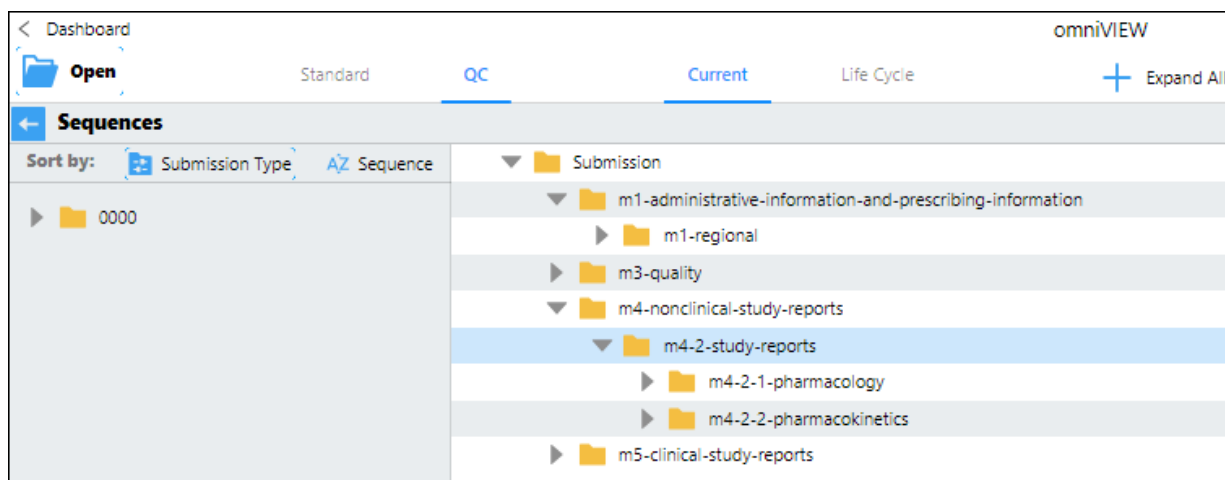


Figure 15: Validating a Sequence

2. Click **Validate Sequence**.

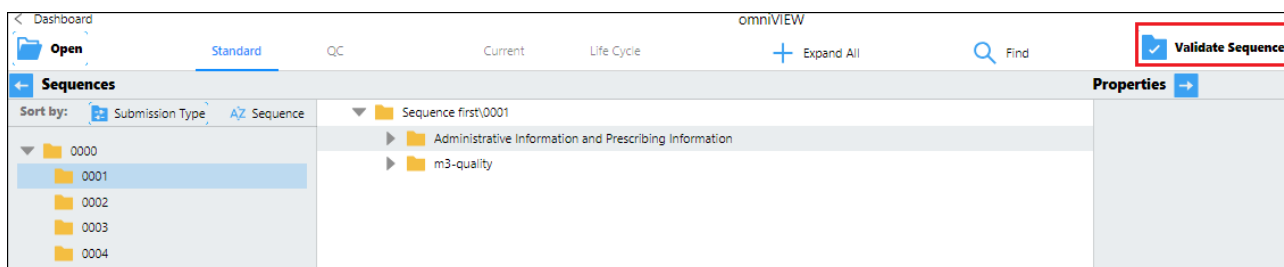


Figure 16: Validate Sequence

The eCTD Sequence Validation window appears with a list of low, medium, high errors.

eCTD Sequence Validation [ind069197\0005]				
Node	Error	Severity	Description	
ind069197\0005 (other) 2010.05.18	1130	Low	Required file checksum value in the util fold...	
ind069197\0005 (other) 2010.05.18	9020	Low	Required file checksum value in the util fold...	
US Regional	1314	Medium	This submission type cannot have a related...	
fda form 1571	5030	High	Application number in form does not match...	
fda form 1571	5045	Medium	PDF opening settings not optimal [PDF ope...	
2010may18 cover letter ae	5045	Medium	PDF opening settings not optimal [PDF ope...	
C935788012 ICSR 2010SE20765 15-day	5005	Medium	Non standard font [not embedded] [Non-sta...	
C935788012 ICSR 2010SE20765 15-day	5045	Medium	PDF opening settings not optimal [PDF ope...	
C935788012 ICSR 2010SE20765 15-day	5045	Medium	Non-required file exists [invalid file: util\st...	
c-935788-012 - C-935788-012	1953	Low	STF XML title and leaf elemnt title do not m...	
c-935788-012 - C-935788-012	1953	Low	STF XML title and leaf elemnt title do not m...	

Figure 17: Validation Errors

Note: The high and medium severity errors must be fixed to submit the sequences without any issues. Click on the file or node to go to the location where the file or node folder is available. Ensure that you address each error by going back to the submission project structure in OmniFILE.

- (Optional) To save the validation report, click **View Report**. OmniVIEW displays the validation report in Microsoft Word document (in .htm format).

What are the Different Modes Available in OmniVIEW?






Following are the different modes available in OmniVIEW:

- **Standard Mode:** In this mode, you can view the node names as readable titles. For example, the XML heading '*m4-nonclinical-study-reports*' is displayed as '*Nonclinical Study Report*'. By default, the sequence of an application opens in the **Standard Mode**. This mode aggregates STFs into studies and study files grouped by file tag.
- **QC Mode:** In this mode, you can view:
 - The submissions based on the pure or true format of each XML backbone file.
 - The XML heading elements with their XML element names (as per the ICH DTD).
 - The STFs in non-aggregation format.
 - The study files in flat structure.

What are the Different Display Options Available in OmniVIEW?

OmniVIEW supports two display views in both Standard and QC mode, as follows:

- **Current View:** This view displays only the current version of the file.
- **Life Cycle View:** This view displays the list of amendments performed on a node or a file. You can view the revision of a file distributed across multiple submissions under the appropriate module folder. The status of each leaf element will be displayed as a different color for each operation type. Refer below table for reference:

Symbol	Document Operation	Designated Color
	New	White
	Replace	Red
	Append	Yellow
	Delete	Black
	STF	Green

Example:

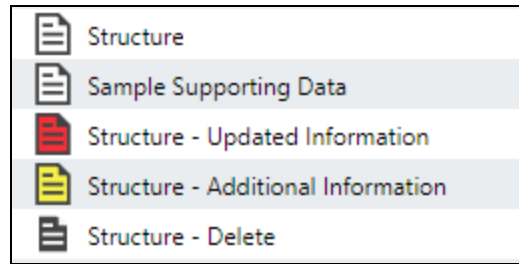


Figure 18: Node Color Coding

What are the Available Sorting Options?

Following are the available sorting options:

- **List by Submission Type:** The Submission Type view displays the relationship between submissions as parent-child based on <submission-type> and <related-sequence> attribute values assigned to each us-regional.xml file. By default, the eCTD sequence folders will be listed by submission type.

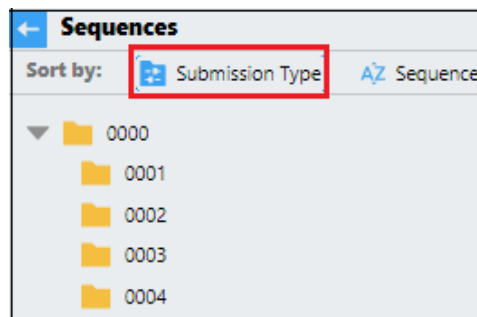


Figure 19: List by Submission Type

- **List by Sequence:** The Sequence Type view displays folders in ascending numerical order. To arrange the folders in descending order, click Sequence again.

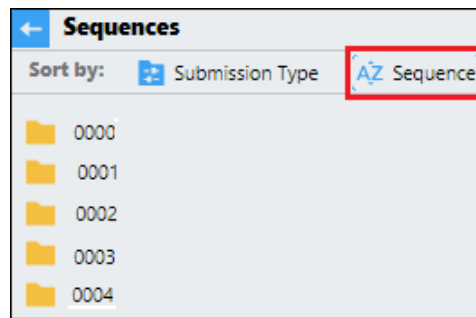


Figure 20: List by Sequence Type

What are the Acronyms and Abbreviations Available in OmniVIEW?

eCTD	Electronic Common Technical Document
MVP	Minimum Viable Product
OAdmin	Omnicia Admin
OP	Omnicia Publisher
OA	Omnicia Author
CAdmin	Customer Admin
CP	Customer Publisher
CA	Customer Author
DTDs	Document Type Definitions

What are the Supported Browsers and Devices?

Browsers	Versions
Google Chrome	72.0.3626.109
Safari	11 and above
Mozilla Firefox	65.0.1
Devices	Size
iPad	Screen size 9.7 and above

What are the Supported User Roles?

OmniVIEW supports the following user roles:

- **Omnicia Users**
 - **Omnicia Publishers (OP):** An Omnicia Publisher can access submissions of all the customers of Omnicia.
 - **Omnicia Authors (OA):** An Omnicia Author can access a sequence, folder, study file and so forth of the customers that are assigned by an Omnicia Administrator or Omnicia Publisher.
- **Customer Users**
 - **Customer Admin (CAAdmin):** A Customer Administrator is usually the owner of an organization. A CAAdmin is responsible to maintain Customer Publishers (CP) and Customer Authors (CA) of an organization. A CAAdmin can access all the submissions of an organization.
 - **Customer Publisher (CP):** A Customer Publisher can access all submissions, create new submissions (via OmniFile), or upload new submissions of their company. A CP can share part of the submissions with Customer Authors within the same company.
 - **Customer Author (CA):** A Customer Author can perform the following:
 - Create documents for eCTD.
 - Review eCTD output produced by an eCTD publisher.

CA can access only that portion of submission that was shared to them by a CP.