EURS 7.2 and EURSvalidator 10.2 – Supported Validation Sets and Functionality

1 Supported Validation Sets

The following table provides a summary of the available validation sets (x) in EURS and EURSvalidator.

Validation Set Name	EURS	EURSvalidator										
		Bulk License Packages		Regional License Packages							Other License Packages	
		Global	EU Unlimited	EU North; EU Central; EU West; EU South; EU UK & Ireland*	EU East*	Switzerland	North America	Asia Pacific	South Africa	Vet Global	Best Practice**
AU-eCTD v3.0.1 (Schema 3.0)	X	X							X			
AU-eCTD v3.1 (Schema 3.1)	X	X							X			
AU-NeeS v3.0	X	X							X			
AU-NeeS v3.1	X	X							X			
CA-eCTD v1.0 (Schema 2.2)	X	X						X				
CA-eCTD v1.0 (DTD 1.0)	X	X						X				

CA-eCTD v3.0 (DTD 1.0 and Schema 2.2)	X	X					X	
CA-eCTD v4.0 (Schema 2.2)	X	X					X	
CA-eCTD v4.1 (Schema 2.2)	X	X					X	
CA-eCTD v4.2 (Schema 2.2)	X	X					X	
CA-eCTD v4.3 (Schema 2.2)	X	X					X	
CA-eCTD v4.4 (Schema 2.2)	X	X					X	
CA-eCTD v4.4 (Schema 2.2)	X	X					X	
CA-eCTD v5.0 (Schema 2.2)	X	X						
CA-eCTD v5.1 (Schema 2.2)	X	X						
CA-Non eCTD Profile-4.2	X	X					X	
CA-Non-eCTD Electronic-Only v4.4	X	X					X	
CA-Non-eCTD Electronic-Only v5.0	X	X						
CA-Non-eCTD Electronic-Only v5.1	X	X						
CH-eCTD v1.0 (DTD 1.0/1.0.1)	X	X				X		
CH-eCTD v1.1 (DTD 1.1)	X	X				X		
CH-eCTD v1.2 (DTD 1.2)	X	X				X		
CH-eCTD v1.3 (DTD 1.3)	X	X				X		
CH-eCTD v1.4 (DTD 1.3)	X	X				X		
CH-eCTD v1.5 (DTD 1.3)	X	X				X		
CN-eCTD v1.0	X	X						X
eCopy v1.1	X	X					X	
EU-eCTD v2.0 (DTD 1.2.1)	X	X	X	X	X			

EU-eCTD v2.1 (DTD 1.3)	X	X	X	X	X					
EU-eCTD v2.1 (DTD 1.4)	X	X	X	X	X					
EU-eCTD v3.1 (DTD 1.4)	X	X	X	X	X					
EU-eCTD v3.1 (DTD 1.4) FAST	X	X	X	X	X					
EU-eCTD v4.1 (DTD 1.4)	X	X	X	X	X					
EU-eCTD v4.1 (DTD 1.4) FAST	X	X	X	X	X					
EU-eCTD v5.0 (DTD 2.0)	X	X	X	X	X					
EU-eCTD v6.1 (DTD 3.0)	X	X	X	X	X					
EU-eCTD v6.1 (DTD 3.0.1)	X	X	X	X	X					
EU-eCTD v7.1 (DTD 3.0.1)	X	X	X	X	X					
EU-NeeS v1.0	X	X	X	X	X					
EU-NeeS v2.1 – Submission Only	X	X	X	X	X					
EU-NeeS v3.0	X	X	X	X	X					
EU-NeeS v4.0	X	X	X	X	X					
EU-NeeS v4.1	X	X	X	X	X					
EU-NeeS v4.3	X	X	X	X	X					
EU-vNeeS V3.0 Immunological Product, Pharmaceutical Product, MRL application, biological product, single file	X	X							X	
EU-PDF BP v1.0 (eCTD v6.1)	X									X
FDA-eCTD CAR v2.2 (DTD 2.01, vv2.2, vv3.0)	X	X				X				
FDA-eCTD v1.0 (DTD 2.01)	X	X				X				

FDA-eCTD v1.0 (DTD 2.01) FAST	X	X				X			
FDA-eCTD v2.2 (DTD 2.01, vv2.2)	X	X				X			
FDA-eCTD v2.2 (DTD 2.01, vv2.2) FAST	X	X				X			
FDA-eCTD v2.2 (DTD 2.01, vv3.0)	X	X				X			
FDA-eCTD v2.2 (DTD 2.01, vv3.0) FAST	X	X				X			
FDA-eCTD v3.1 (DTD 2.01, DTD 3.3)	X	X				X			
FDA-eCTD v3.3 (DTD 2.01, DTD 3.3)	X	X				X			
FDA-eCTD v3.6 (DTD 2.01, DTD 3.3)	X	X				X			
FDA-eCTD v3.7 (DTD 2.01, DTD 3.3)	X	X				X			
FDA-eCTD v3.8 (DTD 2.01, DTD 3.3)	X	X				X			
FDA-eCTD v3.8 (DTD 2.01, DTD 3.3) FAST new	X	X				X			
FDA-eCTD v4.2 (DTD 2.01, DTD 3.3)	X	X							
FDA-eCTD v4.3 (DTD 2.01, DTD 3.3) CDER and CBER	X	X							
FDA-eCTD v4.4 (DTD 2.01, DTD 3.3) CDER and CBER	X	X							
GCC-eCTD v1.0 (DTD 1.0)	X	X					X		
GCC-eCTD v1.2 (DTD 1.0)	X	X					X		
GCC-eCTD v1.4 (DTD 1.1)	X	X					X		
GCC-vNeeS v4.0	X	X					X	X	
HR-eCTD v2.1 (DTD 1.4)	X	X	X		X				
HR-eCTD v3.1(DTD 1.4)	X	X	X		X				

HR-NeeS v1.0	X	X	X		X		
HR-NeeS v2.1 – Submission Only	X	X	X		X		
JO-eCTD v1.0 (DTD 1.0)	X	X			X		
JO-eCTD v1.1 (Schema 1.0)	X	X			X		
JP-eCTD v1.0 (Schema 1.0)	X	X			X		
KSA-NEES v1.0	X	X			X		
KSA-NEES v1.2	X	X			X		
KSA-NEES v1.4	X	X			X		
MCC-eCTD v1.0 (DTD 1.0)	X	X				X	
MCC-eCTD v2.1 (DTD 2.1)	X	X				X	
ZA eSubmission v1.0	X	X				X	
TH-eCTD v1.0 (Schema 1.0)	X	X			X		
TW-eCTD v1.0	X	X			X		
VMD-eNTA (immunological product) DTD 0.9	X	X					X
VMD-eNTA (pharmaceutical product) DTD 0.9	X	X					X
vNeeS (immunological product) v2.2	X	X					X
vNeeS (immunological product) v2.3	X	X					X
vNeeS (immunological product) v2.4	X	X					X
VNeeS (immunological product) v2.5b	X	X					X
VNeeS (immunological product) v2.6	X	X					X
vNeeS (MRL application) v2.2	X	X					X

vNeeS (MRL application) v2.3	X	X											X
vNeeS (MRL application) v2.4	X	X											X
VNeeS (MRL application) v2.5b	X	X											X
VNeeS (MRL application) v2.6	X	X											X
vNeeS (pharmaceutical product) v2.2	X	X											X
vNeeS (pharmaceutical product) v2.3	X	X											X
vNeeS (pharmaceutical product) v2.4	X	X											X
VNeeS (pharmaceutical product) v2.5b	X	X											X
VNeeS (pharmaceutical product) v2.6	X	X											X
vNeeS (single file) v2.4	X	X											X
VNeeS (single file) v2.5b	X	X											X
VNeeS (single file) v2.6	X	X											X
vNeeS 1.0 (immunological product)	X	X											X
vNeeS 1.0 (pharmaceutical product)	X	X											X

* Restrictions apply: the EU regional license packages can be used for validating submissions for the licensed countries only
**More sets available upon request; customize your own validation sets

2   Functionality

Summary overview of EURS and EURSvalidator functionality.

Functionality	Description	EV	EURS
Selection of validation sets			
Turn on/off validation sets	In the Options dialog box the user can select or deselect validation sets to be enabled or disabled respectively. By default, all licensed validation sets are displayed. (EURS: optional by custom configuration)	X	(X)
Validation set/DTD Autoselector	EURSvalidator detects and selects the applicable validation sets automatically (not for NeeS submissions!). If one or more applicable validation sets were found, EURSvalidator chooses the current validation standard automatically. However, the user still may select one of the detected validation set manually from the Validation Set drop-down list. After the initial installation, the newest versions of the validation sets are selected by default. Users may change these defaults according to their requirements. These settings will be preserved after upgrades or re-installation of the software. If desired, a user may always revert to the default selection.	X	X
Fast Validation Sets	Fast validation sets are sets reduced to minimal needed criteria to enable validation within a few seconds.	X	X
Administration			
Display envelope information in the envelope tab page	Envelope attributes of the submission that is currently selected in the Submission Explorer, is displayed in the Envelope Tab Page of the Information Explorer.	X	X
User Management	The User Management features enables the Super Administrator and other system administrators to manage the users of the system, and assign appropriate rights to them by means of permissions, roles, groups, and user accounts.		X
Add Annotations	An annotation is an addition made to information to a table of content (TOC annotation) or to a submission document (PDF annotation). It may be used to add notes about the quality or status of a document at a certain point or to just underline or highlight passages.		X
Viewing			
Envelope Viewing	Display of envelopes in the Submission Explorer according to country selection.	X	X

Different lifecycle management views	Cumulative View: Displays submitted documents in an overall cumulated view with all extensible sections and documents. This is the standard view, no filters have been activated. Current View (with country filter): Currently active documents identified by sequence number Delta View: Documents as well as their associated sections and extensible sections that have been added or changed within the current submission in comparison with the parent submission, are displayed. Regulatory (Sequence) View: Displays files in the current regulatory activity (including sequence numbers) enables, controlling the complete life cycle of a dossier with hundreds of submissions in a selective way.		X
Document Viewer	The Document Viewer displays a currently opened document (PDF, DOC, Multi documents etc.) The cascading function enables to display multiple documents each in a separate window.		X
View submission without validation	Optional provided functionality to access easy viewing of a submission in its structure without validation.		X
Document History/ Lifecycle	All lifecycle operations can be displayed or filtered by the tool. Links, comments and highlights can be set at any time during compilation since documents are referenced relative to a structure element with not changing Applicants original provided document content. The lifecycle status documents is clearly highlighted in the Submission Explorer with the document icons from the table above and different colours of the extensible sections and document names (colour coding for new applied changes for easy recognition of new applied changes).		X
Search functionality	EURS provides an overall and powerful search engine that allows full text search in table of content elements, documents, eCTD-envelopes, attributes, and annotations, confined to a current project, dossier, submission, module or section.		X

Reporting

PDF Reporting (short+long)	After performing the validation process the user can generate a report for validation results of a selected submission. Reports are generated in PDF format and can be opened, viewed, and printed with any PDF reader program. There are multiple types of report: Short Report: This standard report type contains detected errors only. Long Report: The long report contains detected errors and , additionally, warnings, and detailed information.	X	X
Report auto-save	EURS and EURSvalidator both allow saving a summary or a detailed validation report in the dossier folder automatically.	X	X
Validation			
Open Sequence directly	A validation can be started either from a folder or an index.xml file (eCTD) / a ctd-toc.pdf (NeeS).	X	X
Open from product folder (above 0000)	The Browse for Folder dialog box enables to select submissions and to load them within EURSvalidator.	X	X
Validate multiple submissions	User can start the validation for all pending submissions in the Submission Explorer simultaneously. All pending submissions that have not been validated yet will be validated simultaneously.	X	X
Validate multiple dossiers	User can start the validation for all pending dossiers in the Submission Explorer simultaneously. All pending dossiers that have not been validated yet will be validated simultaneously.	X	X