

## Compare and Contrast eDV Dashboard & Pinnacle 21 Enterprise *Automated CDISC Compliance is Better than Traditional Manual Checking*



While there are common features between eDV Dashboard and Pinnacle 21 Enterprise, there are also many unique features in eDV Dashboard: Rapid SDTM Compares, Interactive Issues with Drill Down, Issues across SDTMs and cost savings since SDTM compliance checks are by users instead of by studies.

	eDV Dashboard	P21 Enterprise
<b>CDISC Compliance Features: SDTMs and ADaMs</b>		
Measure Compliance Improvements - <i>with each Iteration</i>	*	
Auto Compare previous Compliance Versions (Unchanged, Decreased, Increased) - <i>No Need for Proc Compare Results, P21 Comparisons are limited to metadata only</i>	*	
Interactive and Drill Down to Record Level – <i>by Domain, Issue number</i>	*	
Group and Assign Common Issues and Solutions – <i>by Domain, Issue number</i>	*	
Record Level Review of Issues – <i>view all domain variables</i>	*	
Execute validation on filtered/selected Rules	*	
CDISC, FDA and PDMA Compliance Rules – <i>includes Rejects, Business and Regulatory</i>	*	*
Create and validate define.xml	*	*
SDRG data-driven issues and solutions – <i>with notes to CDM</i>	*	*
Costs – <i>eDV Dashboard has unlimited use across studies per user</i>	\$/ User	\$\$\$\$\$/ Study

# The *Only* Commercial Product Comparable to Pinnacle 21 Enterprise at a Budget eDV Dashboard Technical Specifications and Common FAQs

## Supported Validation Rules

- FDA Validator Rules v1.6
- FDA Validator Rules v1.5 (SDTM, SEND)
- PMDA Validation Rules v4.0 (SDTM, ADaM)
- PMDA Validation Rules v3.0 (SDTM, ADaM)
- CDISC SEND Conformance Rules v4.0
- CDISC SDTM Conformance Rules v2.0
- CDISC ADaM Conformance Rules v4.0
- CDISC Define Conformance Rules for Define 2.0 & 2.1
- PMDA Define Rules v4.0 (SDTM, SEND & ADaM)
- PMDA Define Rules v3.0 (SDTM, SEND & ADaM)
- FDA Rejection Criteria (FDA TRC Rules)
- PointCross Extended checks

## Uses of eDataValidator

- Validate final and interim study data against all SDTM, ADaM & SEND files in any format (CSV, XPT, SAS7BDAT, EXCEL)
- Validate Define.xml (version 1.0, 2.0, 2.1) with PMDA & CDISC Define validation rules
- Validate study data against all published CDISC CT versions, external dictionaries and proprietary CT's
- CLI to integrate to existing applications
- Perform Data Consistency checks on study datasets to verify structural and metadata correctness
- Generate draft SDRG template for SEND and SDTM
- Generate define files
- Converting XPT datasets to an Excel format

## FAQs

How do I access eDataValidator? ▶

What can eDataValidator (eDV) be used for? ▶

How much does eDataValidator cost? ▶

Is eDV 21 CFR Part 11 compliant? ▶

Does PointCross support validation (IQ / OQ / PQ)? ▶

Is there a limit on the number of validation cycles I can run? ▶

Is the Desktop Application included with my eDV SaaS monthly subscription? ▶

Have Sponsors submitted SDTM/ADaM/SEND datasets to regulatory agencies after validating with eDV? ▶

See eDV Dashboard Videos and Common FAQs, <https://pointcrosslifesciences.com/edatavalidator/>