

## Introduction



With mature processes in place for SDTM, ADaM, and SEND development, the next challenge is ensuring that data validation and regulatory compliance are embedded into every dataset refresh rather than treated as a final checkpoint. Integrating continuous validation into standard workflows improves data quality, increases transparency, and reduces the risk of late-stage submission issues.

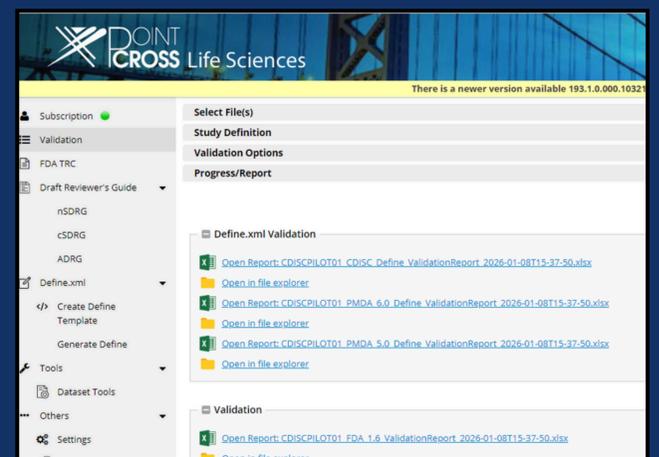
This poster describes an end-to-end validation approach using eDataValidator (eDV), a unified platform for real-time validation of clinical and nonclinical datasets supporting IND, NDA, and BLA submissions. eDV applies FDA, PMDA, and CDISC requirements together with extended PointCross rules to identify compliance issues, paired variable inconsistencies, and data quality concerns as data evolve.

By supporting multiple input formats and automatically generating Define.xml and draft Study Data Reviewer's Guides (SDRGs), eDV streamlines submission deliverables while minimizing manual rework. Integrated quality control dashboards allow teams to track validation results across study versions and domains, enabling in-depth review, reducing false positives, and promoting proactive issue resolution. This workflow-driven validation model enhances collaboration across biometrics, biostatistics, and programming teams using SAS or R, ultimately improving submission readiness throughout the clinical trial lifecycle.

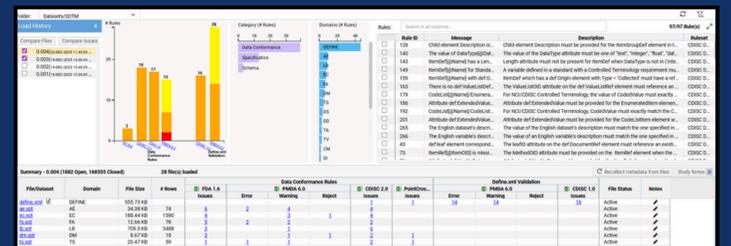
## Key Features



- Supports industry-standard validation rules from CDISC, FDA, and PMDA, with extended rules defined by PointCross
  - FDA (SDTM, SEND)
    - Validator Rules v1.6 & v1.5
  - PMDA (SDTM, ADaM, Define)
    - Validation Rules v6.0, v5.0, v4.0 & v3.0
  - CDISC (SEND, SDTM, ADaM, Define)
    - CDISC SEND Conformance Rules v5.0 & v4.0
    - CDISC SDTM Conformance Rules v2.0
    - CDISC ADaM Conformance Rules v5.0 & v4.0
    - CDISC Define Conformance Rules for Define v2.0 & v2.1
    - CDISC Open Rules Engine (CORE)
- Identify data quality and regulatory compliance issues through validation against established rules, published CDISC controlled terminologies (CT) and external dictionaries.
- Validate datasets across multiple formats, including XPORT (SAS Transport v5), CDISC Dataset JSON (v1.0 and v1.1), Dataset-XML, CSV, SAS7BDAT, and Excel.
- Automatically generate Define.xml directly from the loaded datasets.
- Automatically produce nonclinical, clinical, and analysis Study Data Reviewer's Guides (nSDRG, cSDRG, and ADRG) using dataset content and validation results.



Supports fully offline validation and document generation via a Windows desktop client—running entirely on the user's local system.



Dataset Quality Check Dashboard for reviewing, comparing validation results across study versions and sections.

## Workflow



eDataValidator streamlines the end-to-end clinical data validation workflow - from dataset upload and automated validation to issue resolution, quality tracking, and generation of submission-ready artifacts such as Define.xml and SDRG. This integrated approach ensures data quality, regulatory compliance, and submission readiness while maintaining full traceability throughout the process.



## Why eDataValidator



- Supports unlimited validation cycles across unlimited studies.
- Enables custom rule development based on user-specific requirements.
- Demonstrates lower false-positive rates compared to alternative validation tools.
- PointCross Extended Rules validation check based on FDA Business Rules and FDA Technical Conformance Guide (TCG).
- Available as a cloud-based SaaS solution with an integrated Windows desktop client, enabling both online and offline validation workflows.
- Validated >10,000 submission datasets (SEND, SDTM, ADaM, Define.xml) with zero technical rejections and no non-conformance findings.

## How to Access



eDataValidator can be accessed via a 30-day free trial available on the PointCross website, just scan the QR code.

## Conclusion



eDataValidator enables compliant, high-quality regulatory submissions through comprehensive CDISC and regulatory validation with automated documentation, improving efficiency and submission readiness for biometrics teams.

