



Case Study: Leveraging CDISC CORE for Proactive SDTM Compliance and Submission Readiness

PHUSE USCONNECT 2026, Austin

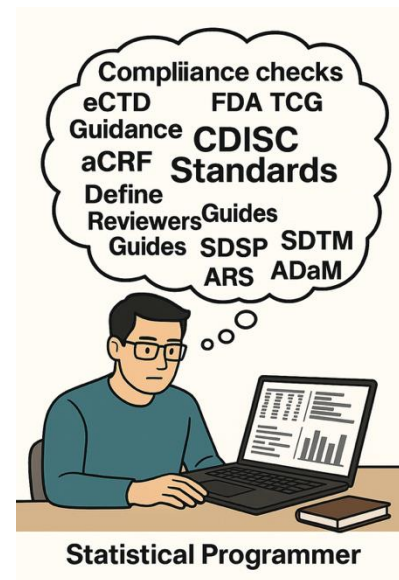
Paper & Presentation # DSo8

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The Bottleneck

- Regulatory submissions require more than quality datasets.
- Compliance, traceability, and transparency are key.
- Challenges include late validation, fragmented workflows, and high manual effort.
- Manual and inconsistent CDISC rule checks.
- Reliance on a single commercial solution.
- Delays and risk of submission rejection.

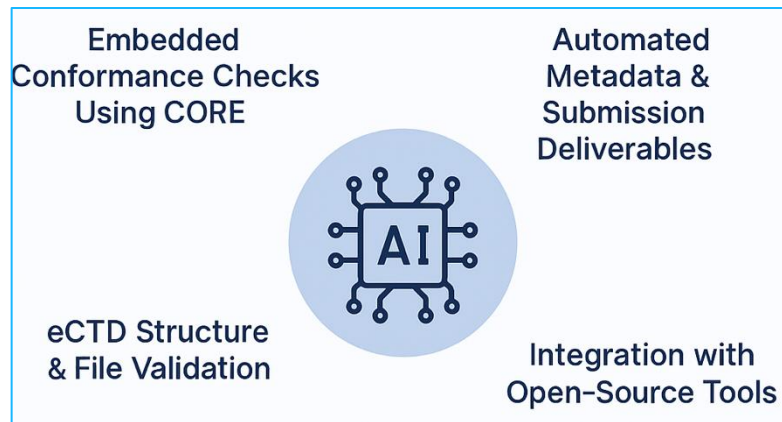


The need for an integrated submission-ready data pipeline!

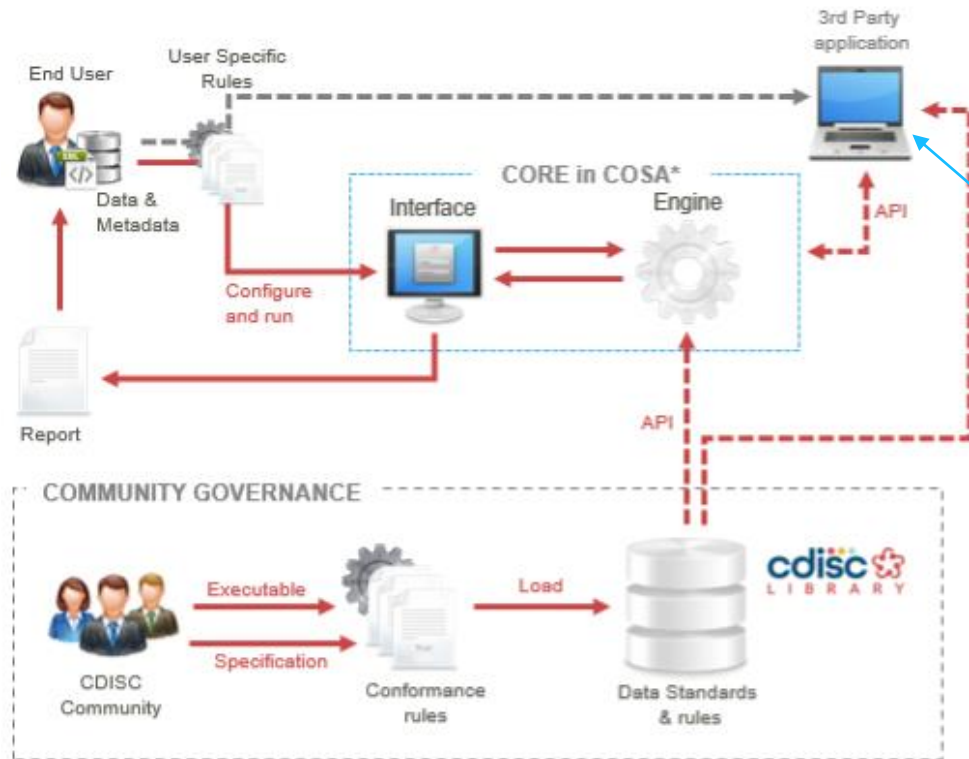
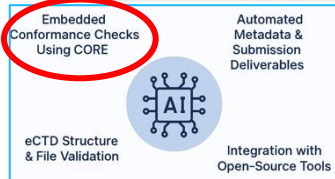
Our Vision

■ **SUBMIFY:** An AI-integrated, modular, standards-driven, and open-source-enabled platform.

- Integrates all critical components of submission data preparation into single, automated pipeline.
- Supports the full lifecycle of SDTM and ADaM dataset development, validation, and regulatory packaging.



Embedded Conformance Checks using CORE Framework



Submify –
embedded
conformance
checks

* CDISC Open-Source Alliance

Reference: <https://www.cdisc.org/core>

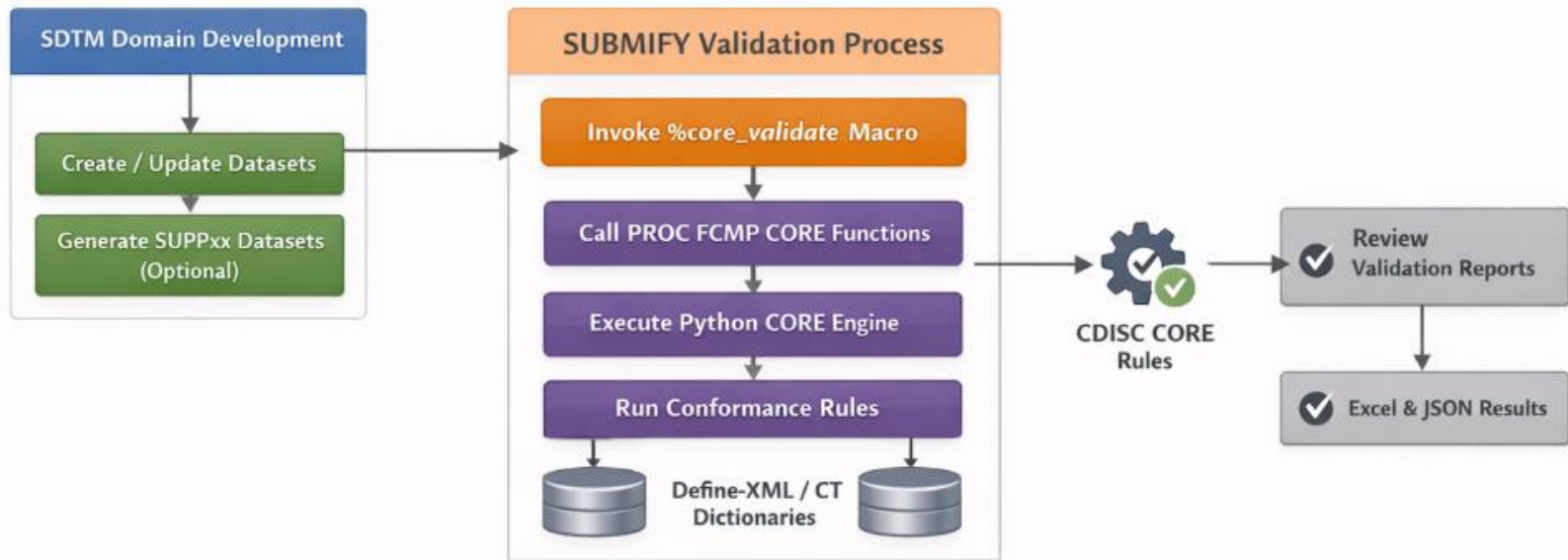
Implementation of CDISC CORE in BASE SAS® Environment

- Cloning the GitHub repository `cdisc-core-sas`, which accompanies the PharmaSUG SD-044 paper.
- Make sure that Python is installed in the PC.
- Follow the installation steps from the paper (create virtual environment, install their dependencies, create the system environment variables).
- Update provided macro call from program `create_core_functions.sas` based on the paper's instruction and run it once.
- Update program `config.sas` based on the paper's instruction. Include this program in all other programs from subsequent steps.

Implementation of CDISC CORE in BASE SAS® Environment

- Create the program containing all the supporting macro calls (core_update_cache, core_list_ct, core_list_rule_sets, core_list_rules based on the paper's instruction. Name of the program: core_update_all.sas.
- Set up the automatization to run core_update_all.sas once a week to get the latest sets of rules and update the solution metadata.
- Create hidden folder for temporary files _temp in the main location.
- Create a core_validate.sas program based on the core_validate_data.sas

SUBMIFY CORE Validation Macro



SUBMIFY CORE Validation Macro

- The %core_validate macro is a central component of the SUBMIFY solution and provides integrated, standards-based validation of clinical datasets during both development and quality control (QC).
- Its primary purpose is to enable early and continuous conformance checking against CDISC and FDA requirements, thereby reducing downstream validation risk and improving overall data quality.
- The macro supports “on-the-fly” validation of SDTM domains as they are created or updated. By identifying conformance issues early in the development lifecycle, %core_validate streamlines the final delivery phase. Early issue detection significantly reduces the likelihood of unexpected findings during final conformance checks.

SUBMIFY CORE Validation Macro

Use of the %core_validate macro follows a standardized three-step process:

■ Setup

A study-level setup file is configured to include the CORE configuration program, define study-specific macro variables, and make the validation macro available within the SAS session.

■ Execution

The %core_validate macro is executed at the end of SDTM domain programs, with parameters specifying the domain, CDISC standard, and standard version.

■ Review

Validation reports are reviewed, issues are addressed, and programs are rerun as needed until conformance is achieved.

SUBMIFY CORE Validation Macro

Macro Parameters and Validation Scope

- The `%core_validate` macro supports required parameters for domain name, CDISC standard, and standard version, along with optional parameters for report timestamping and controlled terminology specification. Each invocation validates a single domain. If a corresponding supplemental qualifier dataset (SUPPxx) exists, it is automatically included in validation.
- The current implementation supports SDTM validation only. Some CORE rules require related domains (e.g., DM or EX) for cross-domain consistency checks; therefore, reports may reference findings from domains not yet available. Such findings may be disregarded when outside the scope of the current validation.

SUBMIFY CORE Validation Macro

Study Setup and Configuration

- To enable CORE validation, the study setup file includes the CORE configuration program and defines study-specific macro variables that establish access to CORE metadata libraries and execution settings. Key macro variables include:
 - `core_outpath`: Output location for CORE validation reports
 - `sdtm_version`: SDTMIG version used for validation
 - `ct_version`: Controlled terminology package version, when applicable

Per-domain validation compared with traditional study-level validation approach

Example: Vitals (VS)

■ Traditional study-level validation

- VS validated only after all SDTM domains are finalized
- Common findings: missing required variables (VSSTRESC, VSTESTCD), invalid controlled terminology, inconsistent units, and visit/timing misalignment with DM/SV
- Late corrections require re-derivation, reprocessing, and full re-validation, often triggering new downstream issues

■ Per-domain validation using CORE

- CORE validation executed immediately after VS creation
- Early detection of missing variables, invalid terminology, unit inconsistencies (e.g., mmHg), and missing numeric results (VSSTRESN)
- Cross-domain issues (USUBJID validity, visit/date alignment with DM and SV) identified while VS programming is active
- Results in fewer end-of-study findings, reduced rework, and faster delivery of submission-ready SDTM

Empowering Pharma & Biotech with Smarter, Faster Submission Process

- **Early, embedded validation:** SUBMIFY CORE shifts conformance checking from late-stage, study-level validation to continuous, per-domain validation during SDTM development, enabling issues to be identified and resolved as datasets are created.
- **Reduced rework and faster corrections:** Immediate, domain-specific validation with %core_validate prevents propagation of structural, terminology, and rule-based errors, improves issue localization, and significantly shortens root-cause analysis and correction cycles.
- **Faster path to submission readiness:** Alignment with official CDISC and FDA rules, combined with configuration-driven consistency and transparent rule logic, results in fewer end-of-study findings, shorter timelines, and more predictable delivery of submission-ready SDTM.

Empowering Pharma & Biotech with Smarter, Faster Submission Process



Accelerating
Timelines



Enhancing
Data Quality



Improving
Collaboration



Mitigating
Risks



Reducing
Costs

Questions ??



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