USDM Validation Packages

The CDISC Unified Study Definition Model (USDM) supports a flexible range of study content, accommodating legacy studies, partial study designs, and diverse design approaches across the industry and therapeutic areas. ClinLine now provides validation packages to efficiently support your use cases.

The USDM CORE validation rules published by CDISC alongside the USDM model can be applied to the USDM API output to assess whether the structure and minimal logical content requirements are met.

Through our work helping technology vendors and pharmaceutical companies implement the USDM, ClinLine identified a need for additional validation packages that extend the existing core rule set to address specific implementation requirements and use cases. We are proud to announce that we will make the following rule packages available to industry under our new licensing structure:

Validation packages at a glance

1. USDM extension rules
2. SDTM Trial Design Domain requirement rules
3. SDTM and EDC automation requirement rules
4. Oncology study SoA (cycles) requirement rules
5. Protocol content rules
6. CTIS and ClinicalTrials.gov registry requirements

Each package includes

- Rule descriptions, error messages, and USDM references
- Fully validated technical implementations of the rules which can be run in the CDISC CORE engine
- The ability to run the additional package as a subset on top of the CORE engine USDM rules
- 2 hours of SME guidance for implementing and/or evaluating the output
- A license to run the rules for 12 months including updates based on feedback and new insights

In addition, ClinLine can also provide

- Direct rule implementation support in additional formats (SQL, JSONata, Python, etc)
- Custom rule development based on specific company use cases
- USDM and digital data flow consultancy
- SME pool ensuring the correct representation of the actual protocol from a content perspective

Let's discuss your next step

Tell us what you want to achieve with digital study information. Together, we can customize the services and initial activities that best support your priorities.

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