Package: openstudyval (via r-universe)

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Type Package

Title Open Validator for FDA Study-Data Submissions

Version 0.1.1

Description Validates clinical and nonclinical study-data packages against publicly described FDA technical-rejection criteria, SAS XPORT constraints from the Study Data Technical Conformance Guide, and an extensible catalog of SDTM, SEND, and ADaM structural conformance checks. Reads a study folder of CSV, RDS, or (when the suggested package haven is installed) SAS v5/v8 transport files, optionally checks define.xml, and writes a submission-style HTML and CSV validation report. This package is an independent open-source implementation. It is not affiliated with, endorsed by, or a copy of Pinnacle 21, Certara, or the FDA.

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URL https://github.com/shekharchalwadigrepo-hub/openstudyval

BugReports https://github.com/shekharchalwadigrepo-hub/openstudyval/issues

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`openstudyval-package` *Open validator for FDA study-data submissions*

Description

Validates a study folder against publicly described FDA technical-rejection criteria, SAS XPORT constraints, and an extensible SDTM, SEND, and ADaM structural catalog. Independent of Pinnacle 21 and not an FDA certification.

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See Also

`validate_submission`, `rules_catalog`

`example_study` *Path to a bundled example study*

Description

Example studies intentionally contain conformance issues so a first validation run produces a non-empty report.

Usage

```
example_study(which = c("sdtm", "adam"))
```

Arguments

`which`	`"sdtm"` or `"adam"`.

Value

Character path to the example directory.

Examples

```
example_study("sdtm")
```

---

osv_report — *Validation report object*

Description

An `osv_report` contains issue rows, a dataset inventory, the standard, and the engine label. Severity order is Reject, Error, Warning, Note.

Usage

```
## S3 method for class 'osv_report'
print(x, ...)

## S3 method for class 'osv_report'
summary(object, ...)

## S3 method for class 'osv_report'
as.data.frame(x, row.names = NULL, optional = FALSE, ...)
```

Arguments

`x, object`	An `osv_report`.
`row.names`	Ignored. Present for the `as.data.frame` generic.
`optional`	Ignored. Present for the `as.data.frame` generic.
`...`	Passed to further methods.

Value

`summary` returns a data frame of one row per rule. `as.data.frame` returns the issue-level data frame.

Examples

```
report <- validate_submission(example_study("sdtm"), standard = "SDTM")
print(report)
as.data.frame(report)
```

read_study_data *Read a study-data folder*

Description

CSV and RDS files are read with base R. SAS transport files (`.xpt`) are read with **haven** when that package is installed.

Usage

```
read_study_data(path)
```

Arguments

`path`	Directory containing study datasets, or a character vector of file paths.

Value

A named list of data frames. Each element has a `source_file` attribute. Names are the upper-case file stem.

Examples

```
study <- read_study_data(example_study("sdtm"))
names(study)
```

rules_catalog *Rule catalog helpers*

Description

The catalog is an original implementation of publicly described expectations. Messages are not copied from Pinnacle 21 or from CDISC conformance-rule publications. Supported check types are `dataset_required`, `variable_required`, `codelist`, `iso8601`, `key_unique`, `one_to_one`, `nonmissing`, and `regex`.

Usage

```
rules_catalog(standard = NULL)

explain_rule(rule_id)

add_custom_rules(rules, catalog = rules_catalog())

severity_levels()
```

Arguments

standard	Optional filter: "SDTM", "SEND", "ADaM", "XPT", or "TRC".
rule_id	Rule identifier, such as "SDTM024".
rules	Data frame of additional rules with the catalog columns.
catalog	Catalog to extend. Defaults to rules_catalog().

Value

rules_catalog and explain_rule return a data frame. add_custom_rules returns the combined catalog. severity_levels returns a character vector.

Examples

```
head(rules_catalog("SDTM"))
explain_rule("SDTM024")
severity_levels()
```

---

validate_datasets *Validate datasets already in memory*

Description

Same engine as validate_submission for data already loaded.

Usage

```
validate_datasets(
  datasets,
  standard = c("SDTM", "SEND", "ADaM"),
  define = NULL,
  rules = NULL,
  ct = NULL,
  version_label = "openstudyval 0.1.0",
  path = NULL
)
```

Arguments

datasets	Named list of data frames, as returned by read_study_data.
standard	One of "SDTM", "SEND", or "ADaM".
define	Optional define.xml path.
rules	Optional extra rules.
ct	Optional controlled terminology data frame.
version_label	Report label.
path	Original folder, used only for technical-rejection file checks.

Value

An object of class `osv_report`.

Examples

```
study <- read_study_data(example_study("adam"))
validate_datasets(study, standard = "ADaM")
```

---

validate_submission *Validate a study-data folder*

Description

Reads datasets, then runs XPORT constraints, standard-specific structural checks, the built-in rule catalog, technical-rejection criteria, and an optional define.xml cross-check.

Usage

```
validate_submission(
  path,
  standard = c("SDTM", "SEND", "ADaM"),
  define = NULL,
  rules = NULL,
  ct = NULL,
  version_label = "openstudyval 0.1.0"
)
```

Arguments

`path`	Directory of datasets, or a vector of dataset files.
`standard`	One of `"SDTM"`, `"SEND"`, or `"ADaM"`.
`define`	Optional path to define.xml. If `NULL`, a file named `define.xml` in `path` is used when present.
`rules`	Optional data frame of extra rules. See `add_custom_rules`.
`ct`	Optional data frame of controlled terminology. Column names are variable names and values are permitted terms.
`version_label`	Character label stored on the report.

Details

The result is not a regulatory certification. Agency engines remain the reference for a live submission.

Value

An object of class `osv_report`.

See Also

validate_datasets, write_validation_report

Examples

```
report <- validate_submission(example_study("sdtm"), standard = "SDTM")
summary(report)
```

---

write_validation_report

Write an HTML or CSV validation report

Description

Writes a submission-style issue summary. The HTML layout is original and is not a Pinnacle 21 report.

Usage

```
write_validation_report(report, file)
```

Arguments

report	An osv_report from validate_submission.
file	Path ending in .html or .csv. An HTML report also writes a sibling CSV.

Value

The written path, invisibly.

Examples

```
report <- validate_submission(example_study("sdtm"), standard = "SDTM")
dest <- file.path(tempdir(), "osv-report.html")
write_validation_report(report, dest)
```

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