

Package ‘openstudyval’

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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>

Encoding UTF-8

Language en-US

Depends R (>= 4.1.0)

Imports stats, tools, utils

Suggests haven, xml2, knitr, rmarkdown, testthat (>= 3.0.0)

VignetteBuilder knitr

Config/testthat/edition 3

RoxygenNote 7.3.2

NeedsCompilation no

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Contents

openstudyval-package	2
example_study	2
osv_report	3
read_study_data	4
rules_catalog	4
validate_datasets	5
validate_submission	6
write_validation_report	7
Index	8

openstudyval-package	<i>Open validator for FDA study-data submissions</i>
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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 Pinna-
cle 21 and not an FDA certification.

Author(s)

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See Also

[validate_submission](#), [rules_catalog](#)

example_study	<i>Path to a bundled example study</i>
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Description

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

Usage

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

Arguments

which "sdm" or "adam".

Value

Character path to the example directory.

Examples

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

osv_report	<i>Validation report object</i>
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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	<i>Read a study-data folder</i>
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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.
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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("sdm"))
names(study)
```

rules_catalog	<i>Rule catalog helpers</i>
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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	<i>Validate datasets already in memory</i>
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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	<i>Validate a study-data folder</i>
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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

<code>report</code>	An osv_report from validate_submission .
<code>file</code>	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)
```

Index

* **package**

openstudyval-package, [2](#)

add_custom_rules, [6](#)

add_custom_rules (rules_catalog), [4](#)

as.data.frame.osv_report (osv_report), [3](#)

example_study, [2](#)

explain_rule (rules_catalog), [4](#)

openstudyval (openstudyval-package), [2](#)

openstudyval-package, [2](#)

osv_report, [3](#)

print.osv_report (osv_report), [3](#)

print.summary.osv_report (osv_report), [3](#)

read_study_data, [4](#), [5](#)

rules_catalog, [2](#), [4](#)

severity_levels (rules_catalog), [4](#)

summary.osv_report (osv_report), [3](#)

validate_datasets, [5](#), [7](#)

validate_submission, [2](#), [5](#), [6](#), [7](#)

write_validation_report, [7](#), [7](#)