Package 'defineR'

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Type Package

Title Creates Define XML Documents

Version 0.0.4

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Description Creates 'define.xml' documents used for regulatory
submissions based on spreadsheet metadata. Can also help
create metadata and generate HTML data explorer.

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R topics documented:

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defineR   *Creates Define XML documents*

Description

The **defineR** package contains functions to create CDISC compliant define.xml documents suitable
for submission to the FDA. The package also contains related capabilities to help create and manage
metadata needed to create the define.xml.

Details

The **defineR** package uses spreadsheet-based metadata. The package can use the metadata to pro-
duce the define.xml, define.html, and a check report. It also has the capability to create a template
to get you started defining metadata for your project.

The **defineR** package is simple to use. It contains only two functions:

- write_define: Creates a define.xml document and related files.
- write_metadata: Creates a metadata template.

See the [Getting Started](https://defineR.r-sassy.org/articles/defineR.html) page for an overview of
these functions. Additional information is available in the function references.

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write_define   *Creates a define XML document*

Description

The write_define function inputs an SDTM or ADAM metadata file and outputs a define.xml and
associated files to a specified directory. Possible associated files are the HTML transformation of
the define.xml and a check report. By default, the check report will also be shown in the viewer.

Usage

```
write_define(
  path,
  dir,
  type = "sdtm",
  ver = NULL,
  check = TRUE,
  html = TRUE,
  view = TRUE,
  report_type = "PDF",
  end_char = ""
)
```

Arguments

path	The path to the metadata file. Currently only Excel metadata files are supported. Other metadata sources may be added if there is sufficient interest.
dir	The output directory to create the define.xml and associated files. If the directory does not exist, the function will attempt to create it.
type	The type of define.xml to create. Valid values are "sdtm" and "adam". Default is "sdtm".
ver	The version of the define XML to produce. Currently only version "2.0.0" is supported.
check	Whether or not to perform consistency checks. If so, a check report will be produced in the output directory. Valid values are TRUE and FALSE. Default is TRUE.
html	Whether or not to produce the HTML output associated with the define.xml. Valid values are TRUE and FALSE. Default is TRUE.
view	Whether or not to show the check report in the viewer. Valid values are TRUE and FALSE. Default is TRUE.
report_type	The output type of the check report, if requested. Valid values are "TXT", "RTF", "PDF", "HTML" and "DOCX". Default is "PDF".
end_char	The end character to use on computational method blocks. These blocks often contain code samples that include line feeds or other line ending characters. This parameter can be used to control how these characters are emitted to the XML parser. Default is an empty string (""). If the line feeds in your computational methods are not working, trying using a return ("\r") or new line ("\n").

Details

The define.xml document is used by the FDA (and others) to review study data. All datasets used in the study are listed, along with variable and value metadata, where clauses, and more. The define.xml can be used along with an XSLT style sheet to transform the XML into an HTML report. This HTML report has links that allow you to easily navigate the data structures.

The write_define function creates both the define XML and the define HTML. The path parameter identifies the location of the Excel metadata, and the dir parameter specifies an output directory. You can create both SDTM and ADAM metadata by passing the appropriate value on the type parameter.

Importantly, the function also produces a check report. This report will compare the define.xml file against the XSD schema supplied by CDISC. Any discrepancies will be written to the check report. By default, the check report is also shown in the viewer, and returned as a vector of strings by the function. This discrepancy list allows you to verify that the metadata has been filled out correctly.

For instance, the conformance check will ensure that each object ID (OID) is unique within the document. Any non-unique IDs will be identified and written to the check report. The check report may therefore be used iteratively to fix the metadata.

Any errors that prevent proper functioning of the procedure will stop execution, and be displayed in the console. All other errors and warnings will be sent to the check report, and will not stop execution.

Note that the check parameter can be used to turn off the conformance check mechanism, and just create the XML.

The XSD schema and XSLT transformation documents were created by CDISC, and are included in the **defineR** package for convenience. To specify another version of the documents, use the options "defineR.xsd" and "defineR.xslt". For example: options("defineR.xsd" = "c:/myproject/define2-1-0.xsd").

Value

The define.xml file and any associated files will be written to the directory specified on the dir parameter.

See Also

[write_metadata](#) to create a metadata template.

Examples

```
# Get temp directory
tmp <- tempdir()

# Create demo metadata
pth <- write_metadata(tmp, demo = TRUE)

# Generate define files
res <- write_define(pth, tmp, view = FALSE)

# View check results
res
# NULL

# View XML
# file.show(file.path(tmp, "define.sdtm.xml"))

# View check report
# file.show(file.path(tmp, "check.sdtm.pdf"))

# View HTML
# file.show(file.path(tmp, "define.sdtm.html"))
```

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write_metadata   *Creates define XML metadata*

Description

The function generates define.xml metadata and writes it to the file system. The function can generate a blank metadata spreadsheet, a demonstration spreadsheet, or metadata read from existing data files. The type parameter can be used to request an SDTM or ADAM spreadsheet.

Usage

```
write_metadata(
  dir,
  type = "sdtm",
  ver = NULL,
  src_dir = NULL,
  check = TRUE,
  demo = FALSE
)
```

Arguments

dir	The directory in which to produce the metadata.
type	The type of metadata file to produce. Valid values are "SDTM" and "ADAM". Default is "SDTM".
ver	The version of the metadata file. Default is the preferred version of the define standard. The function currently supports only version "2.0.0".
src_dir	If the metadata will be generated from existing datasets, supply the directory path for those datasets. If the metadata will not be created from datasets, this parameter should be NULL. Datasets should be in XPT file format.
check	Whether or not to run the checks.
demo	If this parameter is TRUE, the function will generate a metadata file populated with sample data. If the parameter is FALSE, a blank metadata spreadsheet will be produced. Default is FALSE.

Details

Frequently, organizations already have study metadata stored in Excel spreadsheets, and in the correct structure. This structure is used commonly in the industry by other software.

The purpose of the write_metadata function is to create an initial metadata template for studies in which you have no metadata. This task will ensure that you have the proper metadata structure to later create the define.xml.

By default, the function creates an unpopulated metadata spreadsheet. If the demo parameter is set to TRUE, the function will create the same spreadsheet populated with sample data. This sample data can help you to understand how to populate the metadata for your study. Note that this demo spreadsheet is populated correctly, and has no conformance errors. Use this demo spreadsheet as a guide to fill out your metadata.

The demo spreadsheet was created by CDISC, and is included in the **defineR** package for convenience.

Value

The full path of the generated metadata file.

See Also

write_define to create a define.xml document and associated files.

Examples

```
# Get temporary directory
tmp <- tempdir()

# Create demo spreadsheet
out1 <- write_metadata(tmp, demo = TRUE)

# View file
# file.show(out1)

# Create unpopulated spreadsheet
out2 <- write_metadata(tmp, demo = FALSE)

# View file
# file.show(out2)
```

Index