Package 'pvda'

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Type Package

Title Disproportionality Functions for Pharmacovigilance

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add_disproportionality

Add disproportionality estimates to data frame with expected counts

Description

Add disproportionality estimates to data frame with expected counts

Usage

Index

```
add_disproportionality(
  df = NULL,
  df_syms = NULL,
  da_estimators = c("ic", "prr", "ror"),
  rule_of_N = 3,
  conf_lvl = 0.95
)
```

Arguments

df	Intended use is on the output tibble from add_expected_counts.
df_syms	A list built from df_colnames through conversion to symbols.
da_estimators	Character vector specifying which disproportionality estimators to use, in case you don't need all implemented options. Defaults to c("ic", "prr", "ror").
rule_of_N	Numeric value. Sets estimates for ROR and PRR to NA when observed counts are strictly less than the passed value of rule_of_N. Default value is 3, 5 is sometimes used as a more liberal alternative. Set to NULL if you don't want to apply any such rule.
conf_lvl	Confidence level of confidence or credibility intervals. Default is 0.95 (i.e. 95 % confidence interval).

Value

The passed data frame with disproportionality point and interval estimates.

Description

Produces various counts used in disproportionality analysis.

Usage

```
add_expected_counts(
   df = NULL,
   df_colnames = NULL,
   df_syms = NULL,
   expected_count_estimators = c("rrr", "prr", "ror")
)
```

Arguments

df	An object possible to convert to a data table, e.g. a tibble or data.frame, contain- ing patient level reported drug-event-pairs. See header 'The df object' below for further details.	
df_colnames	A list of column names to use in df. That is, point da to the 'report id'-column (report_id), the 'drug name'-column (drug), the 'adverse event'-column (event) and optionally a grouping column group_by to calculate disproportionality across. See the vignette for further details.	
df_syms	A list built from df_colnames through conversion to symbols.	
expected_count_estimators		
	A character vector containing the desired expected count estimators. Defaults to	
	c("rrr", "prr", "ror").	

Value

A tibble containing the various counts.

The df object

The passed df should be (convertible to) a data table and at least contain three columns: report_id, drug and event. The data table should contain one row per reported drug-event-combination, i.e. receiving a single additional report for drug X and event Y would add one row to the table. If the single report contained drug X for event Y and event Z, two rows would be added, with the same report_id and drug on both rows. Column report_id must be of type numeric or character. Columns drug and event must be of type character. If column group_by is provided, it can be either numeric or character. You can use a df with column names of your choosing, as long as you connect role and name in the df_colnames-parameter.

apply_rule_of_N apply_rule_of_N

Description

Internal function to set disproportionality cells for ROR and PRR to NA when observed count < 3

Usage

```
apply_rule_of_N(
    da_df = NULL,
    da_estimators = c("ic", "prr", "ror"),
    rule_of_N = NULL
)
```

Arguments

da_df	See the intermediate object da_df in add_disproportionality
da_estimators	Default is c("ic", "prr", "ror").
rule_of_N	An length one integer between 0 and 10.

Details

Sometimes, you want to protect yourself from spurious findings based on small observed counts combined with infinitesimal expected counts.

Value

The input data frame (da_df) with potentially some cells set to NA.

build_colnames_da An internal function creating colnames for da confidence/credibility bounds

Description

Given the output from quantile_prob, and a da_name string, create column names such as PRR025, ROR025 and IC025

Usage

```
build_colnames_da(
   quantile_prob = list(lower = 0.025, upper = 0.975),
   da_name = NULL
)
```

Arguments

quantile_prob	A list with two parameters, lower and upper. Default: list(lower = 0.025, upper
	= 0.975)
da_name	A string, such as "ic", "prr" or "ror". Default: NULL

Value

A list with two symbols, to be inserted in the dtplyr-chain

ci_for_ic Confidence intervals for Information Component (IC)	
---	--

Description

Mainly used in function ic. Produces quantiles of the posterior gamma distribution. Called twice in ic to create credibility intervals.

Usage

```
ci_for_ic(obs, exp, conf_lvl_probs, shrinkage)
```

Arguments

obs	A numeric vector with observed counts, i.e. number of reports for the selected drug-event-combination. Note that shrinkage (e.g. +0.5) is added inside the function and should not be included here.
exp	A numeric vector with expected counts, i.e. number of reports to be expected given a comparator or <i>background</i> . Note that shrinkage (e.g. $+0.5$) is added inside the function and should not be included here.

conf_lvl_probs	The probabilities of the posterior, based on a passed confidence level (conf_lvl)
	in ic. For instance, if sgn_lvl = .95 in ic is used, quantiles will be extracted
	at sgn_lvl_probs 0.025 and 0.975.
shrinkage	A non-negative numeric value, to be added to observed and expected count. Default is 0.5.

Value

The credibility interval specified by input parameters.

See Also

ic

ci_for_prr

Confidence intervals for Proportional Reporting Rate

Description

Mainly for use in prr. Produces (symmetric, normality based) confidence bounds for the PRR, for a passed probability. Called twice in prr to create confidence intervals.

Usage

```
ci_for_prr(
  obs = NULL,
  n_drug = NULL,
  n_event_prr = NULL,
  n_tot_prr = NULL,
  conf_lvl_probs = 0.95
)
```

Arguments

obs	Number of reports for the specific drug and event (i.e. the observed count).
n_drug	Number of reports with the drug of interest.
n_event_prr	Number of reports with the event in the background.
n_tot_prr	Number of reports in the background.
conf_lvl_probs	The probabilities of the normal distribution, based on a passed confidence level $(conf_lvl)$ in prr. If sgn_lvl = .95 in prr, quantiles of the normal distribution will be extracted at sgn_lvl_probs of 0.025 and 0.975.

Value

The confidence interval specified by input parameters.

ci_for_ror

See Also

prr

ci_for_ror

Confidence intervals for Reporting Odds Ratio

Description

Mainly for use in ror. Produces (symmetric, normality based) confidence bounds for the ROR, for a passed probability. Called twice in ror to create confidence intervals.

Usage

ci_for_ror(a, b, c, d, conf_lvl_probs)

Arguments

а	Number of reports for the specific drug and event (i.e. the observed count).
b	Number of reports with the drug, without the event
С	Number of reports without the drug, with the event
d	Number of reports without the drug, without the event
conf_lvl_probs	The probabilities of the normal distribution, based on a passed confidence level $(conf_lvl)$ in ror. If $sgn_lvl = .95$ in ror, quantiles of the normal distribution will be extracted at sgn_lvl_probs of 0.025 and 0.975.

Value

The credibility interval specified by input parameters.

See Also

ror

```
conf_lvl_to_quantile_prob
```

Quantile probabilities from confidence level

Description

Calculates equi-tailed quantile probabilities from a confidence level

Usage

```
conf_lvl_to_quantile_prob(conf_lvl = 0.95)
```

Arguments

conf_lvl Confidence level of confidence or credibility intervals. Default is 0.95 (i.e. 95 % confidence interval).

Value

A list with two numerical vectors, "lower" and "upper".

Examples

conf_lvl_to_quantile_prob(0.95)

count_expected_prr Count expected for Proportional Reporting Rate

Description

Internal function to provide expected counts related to the PRR

Usage

```
count_expected_prr(count_dt)
```

Arguments

count_dt A data table, output from count_expected_rrr

Value

A data table with added columns for n_event_prr n_tot_prr and expected_prr @export

count_expected_ror Count expected for Reporting Odds Ratio

Description

Internal function to provide expected counts related to the ROR

Usage

```
count_expected_ror(count_dt)
```

Arguments

count_dt A data table, output from count_expected_rrr

Details

DETAILS

Value

A data table with added columns for n_event_prr, n_tot_prr and expected_prr OUTPUT_DESCRIPTION

See Also

mutate, select everything

count_expected_rrr Count Expected for Relative Reporting Rate

Description

Internal function to provide expected counts related to the RRR

Usage

```
count_expected_rrr(df, df_colnames, df_syms)
```

Arguments

df	See documentation for add_expected_counts
df_colnames	See documentation for da
df_syms	A list built from df_colnames through conversion to symbols.

Value

A data frame with columns for obs, n_drug, n_event, n_tot and (RRR) expected

Description

The function da executes disproportionality analyses, i.e. compares the proportion of reports with a specific adverse event for a drug, against an event proportion from a comparator based on the passed data frame. See the vignette for a brief introduction to disproportionality analysis. Furthermore, da supports three estimators: Information Component (IC), Proportional Reporting Rate (PRR) and the Reporting Odds Ratio (ROR).

Usage

```
da(
  df = NULL,
  df_colnames = list(report_id = "report_id", drug = "drug", event = "event", group_by =
    NULL),
  da_estimators = c("ic", "prr", "ror"),
  sort_by = "ic",
  number_of_digits = 2,
  rule_of_N = 3,
  conf_lvl = 0.95,
  excel_path = NULL
)
```

Arguments

df	An object possible to convert to a data table, e.g. a tibble or data.frame, contain- ing patient level reported drug-event-pairs. See header 'The df object' below for further details.	
df_colnames	A list of column names to use in df. That is, point da to the 'report id'-column (report_id), the 'drug name'-column (drug), the 'adverse event'-column (event) and optionally a grouping column group_by to calculate disproportionality across. See the vignette for further details.	
da_estimators	Character vector specifying which disproportionality estimators to use, in case you don't need all implemented options. Defaults to c("ic", "prr", "ror").	
sort_by	The output is sorted in descending order of the lower bound of the confidence/credibility interval for a passed da estimator. Any of the passed strings in "da_estimators" is accepted, the default is "ic". If a grouping variable is passed, sorting is made by the sample average across each drug-event-combination (ignoring NAs).	
number_of_digits		
	Round decimal columns to specified precision, default is two decimals.	
rule_of_N	Numeric value. Sets estimates for ROR and PRR to NA when observed counts are strictly less than the passed value of rule_of_N. Default value is 3, 5 is sometimes used as a more liberal alternative. Set to NULL if you don't want to apply any such rule.	

da

conf_lvl	Confidence level of confidence or credibility intervals. Default is 0.95 (i.e. 95 % confidence interval).
excel_path	Intended for users who prefer to work in excel with minimal work in R. To write the output of da to an excel file, provide a path to a folder. For instance, to write to your current working directory, pass getwd(). The excel file will by default be named da.xlsx. To control the excel file name, pass a path ending with the desired filename suffixed with .xlsx. If you do not want to export the output to an excel file, pass NULL (the default).

Value

da returns a data frame (invisibly) containing counts and estimates related to supported disproportionality estimators. Each row corresponds to a drug-event pair.

The df object

The passed df should be (convertible to) a data table and at least contain three columns: report_id, drug and event. The data table should contain one row per reported drug-event-combination, i.e. receiving a single additional report for drug X and event Y would add one row to the table. If the single report contained drug X for event Y and event Z, two rows would be added, with the same report_id and drug on both rows. Column report_id must be of type numeric or character. Columns drug and event must be of type character. If column group_by is provided, it can be either numeric or character. You can use a df with column names of your choosing, as long as you connect role and name in the df_colnames-parameter.

Examples

Run a disproportionality analysis

```
da_1 <-
 tiny_dataset |>
 da()
### Run a disproportionality across subgroups
list_of_colnames <-</pre>
 list(
    report_id = "report_id",
   drug = "drug",
    event = "event",
    group_by = "group"
 )
 da_2 <-
 tiny_dataset |>
 da(df_colnames = list_of_colnames)
# If columns in your df have different names than the default ones,
# you can specify the column names in the df_colnames parameter list:
renamed_df <-</pre>
 tiny_dataset |>
```

```
dplyr::rename(ReportID = report_id)
list_of_colnames$report_id <- "ReportID"
da_3 <-
    renamed_df |>
    da(df_colnames = list_of_colnames)
```

drug_event_df A simulated ICSR database

Description

drug_event_df is a simulated dataset, slightly larger than the "tiny_dataset" which is also contained in this package.

Usage

drug_event_df

Format

'drug_event_df' A data frame with 3,971 rows and 3 columns. In total 1000 unique report_ids, i.e. the same report_id can have several drugs and events.

Number of drugs per report_id is sampled as 1 + Pois(3), with increasing probability as the drug letter closes in on Z. Every drug is assigned an event, with decreasing probability as the event index number increases towards 1000. See the DATASET.R file in the data-raw folder for details.

report_id A patient or report identifier

drug One of 26 fake drugs (Drug_A - Drug_Z)

event Sampled events (Event_1 - Event_1000)

Source

Simulated data.

grouped_da

Description

A package internal wrapper for executing da across subgroups

Usage

```
grouped_da(
  df = NULL,
  df_colnames = NULL,
  df_syms = NULL,
  expected_count_estimators = NULL,
  da_estimators = NULL,
  sort_by = NULL,
  conf_lvl = NULL,
  rule_of_N = NULL,
  number_of_digits = NULL
)
```

Arguments

df	See the da function
df_colnames	See the da function
df_syms	A list built from df_colnames through conversion to symbols.
expected_count_	_estimators
	See the da function
da_estimators	See the da function
sort_by	See the da function
conf_lvl	See the da function
rule_of_N	See the da function
number_of_digit	ts
	See the da function

Details

See the da documentation

Value

See the da function

Description

Calculates the information component ("IC") and credibility interval, used in disproportionality analysis.

Usage

ic(obs = NULL, exp = NULL, shrinkage = 0.5, conf_lvl = 0.95)

Arguments

obs	A numeric vector with observed counts, i.e. number of reports for the selected drug-event-combination. Note that shrinkage (e.g. $+0.5$) is added inside the function and should not be included here.
exp	A numeric vector with expected counts, i.e. number of reports to be expected given a comparator or <i>background</i> . Note that shrinkage (e.g. $+0.5$) is added inside the function and should not be included here.
shrinkage	A non-negative numeric value, to be added to observed and expected count. Default is 0.5.
conf_lvl	Confidence level of confidence or credibility intervals. Default is 0.95 (i.e. 95 % confidence interval).

Details

The IC is a log2-transformed observed-to-expected ratio, based on the relative reporting rate (RRR) for counts, but modified with an addition of "shrinkage" to protect against spurious associations.

$$\hat{IC} = \log_2(\frac{\hat{O}+k}{\hat{E}+k})$$

where \hat{O} = observed number of reports, k is the shrinkage (typically +0.5), and expected \hat{E} is (for RRR, and using the entire database as comparator or *background*) estimated as

$$\hat{E} = \frac{\hat{N}_{drug} \times \hat{N}_{event}}{\hat{N}_{TOT}}$$

where \hat{N}_{drug} , \hat{N}_{event} and \hat{N}_{TOT} are the number of reports with the drug, the event, and in the whole database respectively.

The credibility interval is created from the quantiles of the posterior gamma distribution with shape (\hat{S}) and rate (\hat{R}) parameters as

$$\hat{S} = \hat{O} + k$$

ic

print.da

$$\ddot{R} = \ddot{E} + k$$

using the stats::qgamma function. Parameter k is the shrinkage defined earlier. For completeness, a credibility interval of the gamma distributed X (i.e. $X \sim \Gamma(\hat{S}, \hat{R})$ where \hat{S} and \hat{R} are shape and rate parameters) with associated quantile function $Q_X(p)$ for a significance level α is constructed as

$$[Q_X(\alpha/2), Q_X(1-\alpha/2)]$$

Value

A tibble with three columns (point estimate and credibility bounds).

Further details

From a bayesian point-of-view, the credibility interval of the IC is constructed from the poissongamma conjugacy. The shrinkage constitutes a prior of observed and expected of 0.5. A shrinkage of +0.5 with a gamma-quantile based 95 % credibility interval cannot have lower bound above 0 unless the observed count exceeds 3. One benefit of log_2 is to provide a log-scale for convenient plotting of multiple IC values side-by-side.

References

Norén GN, Hopstadius J, Bate A (2011). "Shrinkage observed-to-expected ratios for robust and transparent large-scale pattern discovery." *Statistical Methods in Medical Research*, **22**(1), 57–69. doi:10.1177/0962280211403604, https://doi.org/10.1177/0962280211403604.

Examples

```
ic(obs = 20, exp = 10)
# Note that obs and exp can be vectors (of equal length, no recycling allowed)
ic(obs = c(20, 30), exp = c(10, 10))
```

print.da

print function for da objects

Description

print function for da objects

Usage

```
## S3 method for class 'da'
print(x, n = 10, ...)
```

Arguments

х	A S3 obj of class "da", output from pvda::da().
n	Control the number of rows to print.
	For passing additional parameters to extended classes.

Value

Nothing, but prints the tibble da_df in the da object.

Examples

```
da_1 <-
tiny_dataset |>
da()
print(da_1)
```

prr

Proportional Reporting Rate

Description

Calculates Proportional Reporting Rate ("PRR") with confidence intervals, used in disproportionality analysis.

Usage

```
prr(
  obs = NULL,
  n_drug = NULL,
  n_event_prr = NULL,
  n_tot_prr = NULL,
  conf_lvl = 0.95
)
```

Arguments

obs	Number of reports for the specific drug and event (i.e. the observed count).
n_drug	Number of reports with the drug of interest.
n_event_prr	Number of reports with the event in the background.
n_tot_prr	Number of reports in the background.
conf_lvl	Confidence level of confidence or credibility intervals. Default is 0.95 (i.e. 95 % confidence interval).

Details

The PRR is the proportion of reports with an event in set of exposed cases, divided with the proportion of reports with the event in a background or comparator, which does not include the exposed.

The PRR is estimated from a observed-to-expected ratio, based on similar to the RRR and IC, but excludes the exposure of interest from the comparator.

$$P\hat{R}R = \frac{O}{\hat{E}}$$

where \hat{O} is the observed number of reports, and expected \hat{E} is estimated as

$$\hat{E} = \frac{\hat{N}_{drug} \times (\hat{N}_{event} - \hat{O})}{\hat{N}_{TOT} - \hat{N}_{drug}}$$

where \hat{N}_{drug} , \hat{N}_{event} , \hat{O} and \hat{N}_{TOT} are the number of reports with the drug, the event, the drug and event, and in the whole database respectively.

A confidence interval is derived in Gravel (2009) using the delta method:

$$\hat{s} = \sqrt{1/\hat{O} - 1/(\hat{N}_{drug}) + 1/(\hat{N}_{event} - \hat{O}) - 1/(\hat{N}_{TOT} - \hat{N}_{drug})}$$

and

$$\begin{split} [CI_{\alpha/2}, CI_{1-\alpha/2}] = \\ [\frac{\hat{O}}{\hat{E}} \times \exp(Q_{\alpha/2} \times \hat{s}), \frac{\hat{O}}{\hat{E}} \times \exp(Q_{1-\alpha/2} \times \hat{s})] \end{split}$$

where Q_{α} denotes the quantile function of a standard Normal distribution at significance level α .

Note: For historical reasons, another version of this standard deviation is sometimes used where the last fraction under the square root is added rather than subtracted, with negligible practical implications in large databases. This function uses the version declared above, i.e. with subtraction.

Value

A tibble with three columns (point estimate and credibility bounds). Number of rows equals length of inputs obs, n_drug, n_event_prr and n_tot_prr.

References

Montastruc J, Sommet A, Bagheri H, Lapeyre-Mestre M (2011). "Benefits and strengths of the disproportionality analysis for identification of adverse drug reactions in a pharmacovigilance database." *British Journal of Clinical Pharmacology*, **72**(6), 905–908. doi:10.1111/j.13652125.2011.04037.x, https://doi.org/10.1111/j.1365-2125.2011.04037.x.

Gravel C (2009). "Statistical Methods for Signal Detection in Pharmacovigilance." https://repository.library.carleton.ca/downloads/jd472x08w.

Examples

```
prr(
    obs = 5,
    n_drug = 10,
    n_event_prr = 20,
    n_tot_prr = 10000
)
# Note that input parameters can be vectors (of equal length, no recycling)
pvda::prr(
    obs = c(5, 10),
    n_drug = c(10, 20),
    n_event_prr = c(15, 30),
    n_tot_prr = c(10000, 10000)
)
```

ror

Reporting Odds Ratio

Description

Calculates Reporting Odds Ratio ("ROR") and confidence intervals, used in disproportionality analysis.

Usage

ror(a = NULL, b = NULL, c = NULL, d = NULL, conf_lvl = 0.95)

Arguments

а	Number of reports for the specific drug and event (i.e. the observed count).
b	Number of reports with the drug, without the event
с	Number of reports without the drug, with the event
d	Number of reports without the drug, without the event
conf_lvl	Confidence level of confidence or credibility intervals. Default is 0.95 (i.e. 95 % confidence interval).

Details

The ROR is an odds ratio calculated from reporting counts. The R for Reporting in ROR is meant to emphasize an interpretation of reporting, as the ROR is calculated from a reporting database. Note: the function is vectorized, i.e. a, b, c and d can be vectors, see the examples.

A reporting odds ratio is simply an odds ratio based on adverse event reports.

$$R\hat{O}R = \frac{a/b}{c/d}$$

where a = observed count (i.e. number of reports with exposure and outcome), b = number of reports with the drug and without the event, c = number of reports without the drug with the event and d = number of reports with neither of the drug and the event.

A confidence interval for the ROR can be derived through the delta method, with a standard deviation:

$$\hat{s} = \sqrt{1/a + 1/b + 1/c + 1/d}$$

with the resulting confidence interval for significance level α

$$[ROR \times exp(\Phi_{\alpha/2} \times \hat{s}), ROR \times exp(\Phi_{1-\alpha/2} \times \hat{s})]$$

Value

A tibble with three columns (point estimate and credibility bounds). Number of rows equals length of inputs a, b, c, d.

References

Montastruc J, Sommet A, Bagheri H, Lapeyre-Mestre M (2011). "Benefits and strengths of the disproportionality analysis for identification of adverse drug reactions in a pharmacovigilance database." *British Journal of Clinical Pharmacology*, **72**(6), 905–908. doi:10.1111/j.13652125.2011.04037.x, https://doi.org/10.1111/j.1365-2125.2011.04037.x.

Examples

```
ror(
    a = 5,
    b = 10,
    c = 20,
    d = 10000
)
# Note that a, b, c and d can be vectors (of equal length, no recycling)
pvda::ror(
    a = c(5, 10),
    b = c(10, 20),
    c = c(15, 30),
    d = c(10000, 10000)
)
```

round_and_sort_by_lower_da_limit

Sort a disproportionality analysis by the lower da conf. or cred. limit

Description

Sorts the output by the mean lower limit of a passed da estimator

Usage

```
round_and_sort_by_lower_da_limit(
    df = NULL,
    df_colnames = NULL,
    df_syms = NULL,
    conf_lvl = NULL,
    sort_by = NULL,
    da_estimators = NULL,
    number_of_digits = 2
)
```

Arguments

df	See add_disproportionality
df_colnames	See add_disproportionality
df_syms	See add_disproportionality
conf_lvl	See add_disproportionality
sort_by	See add_disproportionality
da_estimators	See add_disproportionality
number_of_digi	ts
	Numeric value Set the num

Numeric value. Set the number of digits to show in output by passing an integer. Default value is 2 digits. Set to NULL to avoid rounding.

Value

The df object, sorted.

Description

Internal function containing a mutate + across

Usage

```
round_columns_with_many_decimals(
    da_df = NULL,
    da_estimators = NULL,
    number_of_digits = NULL
)
```

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summary.da

Arguments

da_df	See add_disproportionality
da_estimators	See add_disproportionality
number_of_digits	
	See add_disproportionality

Value

A df with rounded columns

summary.da

Summary function for disproportionality objects

Description

Provides summary counts of SDRs and shows the top five DECs

Usage

S3 method for class 'da'
summary(object, print = TRUE, ...)

Arguments

object	A S3 obj of class "da", output from pvda::da().
print	Do you want to print the output to the console. Defaults to TRUE.
	For passing additional parameters to extended classes.

Value

Passes a tibble with the SDR counts invisibly.

tiny_dataset A 110 reports big, simulated ICSR database

Description

The dataframe tiny_dataset is used to demonstrate the functionality of the package in examples. The larger drug_event_df-dataset can also be used.

Usage

tiny_dataset

Format

'tiny_dataset' A data frame with 110 rows and 3 columns. In total 110 unique report_ids. In particular, for Drug A and Event 1 the observed count will be 4 and $exp_rrr = 1.1$

report_id A report identifier, 1-110.

drug Drugs named as Drug_A - Drug_Z.

event Events named as Event_1 - Event_97)

group In this example, sex of the patient, i.e. Male or Female.

Source

Simulated data.

write_to_excel Write to excel

Description

Writes output from a disproportionality analysis to an excel file

Usage

```
write_to_excel(df, write_path = NULL)
```

Arguments

df	The data frame to export. See '?da' for details.
write_path	A string giving the file path

Value

Nothing.

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