

Package ‘BE’

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Title Bioequivalence Study Data Analysis

Description Analyze bioequivalence study data with industrial strength. The statistical core is delegated to the 'sasLM' package, which reproduces 'SAS' PROC GLM output; this covers the analysis of variance, the least square means, and the confidence interval of a 2x2 crossover study. Sample size could be determined for various crossover designs, such as 2x2 design, 2x4 design, 4x4 design, Balaam design, Two-sequence dual design, and William design.
Reference: Chow SC, Liu JP. Design and Analysis of Bioavailability and Bioequivalence Studies. 3rd ed. (2009, ISBN:978-1-58488-668-6).

Depends R (>= 3.5.0)

Imports sasLM (>= 1.0.1), rtf

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BE-package	<i>Bioequivalence Study Data Analysis</i>
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Description

Analyze bioequivalence study data with industrial strength. Sample size could be determined for various crossover designs, such as 2x2 design, 2x4 design, 4x4 design, Balaam design, Two-sequence dual design, and William design. Basic assumption is that the variable is distributed as a log-normal distribution. This is SAS PROC GLM style. If you want PROC MIXED style, use nlme::lme.

Details

It performs bioequivalency tests for several variables of a 2x2 study in a data file.
The linear model of a 2x2 crossover study is fitted by the **sasLM** package, which reproduces SAS PROC GLM output; see [test2x2](#). The report file is written with the **rtf** package.

Author(s)

Kyun-Seop Bae <k@acr.kr>

References

1. Chow SC, Liu JP. Design and Analysis of Bioavailability and Bioequivalence Studies. 3rd ed. (2009, ISBN:978-1-58488-668-6)
2. Hauschke D, Steinijans V, Pigeot I. Bioequivalence Studies in Drug Development. (2007, ISBN:978-0-470-09475-4)
3. Diletti E, Hauschke D, Steinijans VW. Sample size determination for bioequivalence assessment by means of confidence intervals. Int J Clinical Pharmacol Ther Tox. 1991;29(1):1-8

Examples

```
# write.csv(NCAResult4BE, "temp.csv", quote=FALSE, row.names=FALSE)
# be2x2("temp.csv", c("AUClast", "Cmax", "Tmax"))
```

be2x2	<i>Bioequivalence test of a 2x2 study</i>
-------	---

Description

It performs conventional bioequivalence test for 2x2 study. Input is a file. Basic assumption is that the variable is distributed as a log-normal distribution. This is SAS PROC GLM style. If you want PROC MIXED style, use nlme::lme.

Usage

```
be2x2(Data, Columns = c("AUClast", "Cmax", "Tmax"), rtfName="")
```

Arguments

Data	A data.frame or a csv file name. This should have at least the following columns and variable column(s) to be tested. AUC and Cmax should be all positive values. GRP : Group or Sequence, 'RT' or 'TR' PRD : Period, 1 or 2 SUBJ : Subject ID TRT : Treatment or Drug, 'R' or 'T'
Columns	Column names of variables to be tested. This is usually c("AUClast", "Cmax", "Tmax") or c("AUClast", "AUCinf", "Cmax", "Tmax")
rtfName	Output filename of rich text format(rtf)

Details

It performs bioequivalency tests for several variables of a 2x2 study in a data file. If you specify output filename in rtfName, the output will be saved in the file.

Value

Returns a named list with one element per column in Columns; each element is the equivalence-test result list from test2x2 (or from hedges for Tmax).

Author(s)

Kyun-Seop Bae <k@acr.kr>

See Also

[test2x2](#), [plot2x2](#)

Examples

```
be2x2(NCAREsult4BE, c("AUClast", "Cmax", "Tmax"))
```

ci2cv	<i>Coefficient of variation (CV) from a confidence interval of previous 2x2 study</i>
-------	---

Description

It calculates coefficient of variation (CV) from a confidence interval of previous 2x2 study.

Usage

```
ci2cv(n1, n2, LL, UL, Alpha = 0.1)
```

Arguments

n1	Subject count of group 1
n2	Subject count of group 2
LL	Lower limit of the confidence interval of geometric mean ratio (Test/Reference)
UL	Upper limit of the confidence interval of geometric mean ratio (Test/Reference)
Alpha	Alpha level. This means $(1 - \alpha/2) \times 100$ % confidence interval is given

Details

It calculates coefficient of variation (CV) from a confidence interval of 2x2 bioequivalence study.

Value

Returns coefficient of variation (CV) in percent (%).

Author(s)

Kyun-Seop Bae <k@acr.kr>

Examples

```
ci2cv(12, 13, 0.85, 1.11)
```

ci2mse	<i>Mean squared error (MSE) from a confidence interval of previous 2x2 study</i>
--------	--

Description

It calculates mean squared error (MSE) from a confidence interval of previous 2x2 study.

Usage

```
ci2mse(n1, n2, LL, UL, Alpha = 0.1)
```

Arguments

n1	Subject count of group 1
n2	Subject count of group 2
LL	Lower limit of the confidence interval of geometric mean ratio (Test/Reference)
UL	Upper limit of the confidence interval of geometric mean ratio (Test/Reference)
Alpha	Alpha level. This means $(1 - \alpha/2) \times 100$ % confidence interval is given

Details

It calculates mean squared error (MSE) from a confidence interval of 2x2 bioequivalence study.

Value

Returns mean squared error (MSE).

Author(s)

Kyun-Seop Bae <k@acr.kr>

Examples

```
ci2mse(12, 13, 0.85, 1.11)
```

`cv2mse`*Mean squared error (MSE) from coefficient of variation (CV)*

Description

It calculates mean squared error (MSE) from coefficient of variation (CV).

Usage

```
cv2mse(cv)
```

Arguments

`cv` Coefficient of variation (%) in the original scale

Details

Coefficient of variation (CV) is percent in original scale and mean squared error (MSE) is log scale.

Value

Returns mean squared error (MSE) in log scale.

Author(s)

Kyun-Seop Bae <k@acr.kr>

Examples

```
cv2mse(25)
```

`hodges`*Hodges-Lehmann estimation for a variable of a 2x2 study*

Description

It performs Hodges-Lehmann estimation for 2x2 study. This is usually for Tmax variable.

Usage

```
hodges(bedata, Var)
```

Arguments

bedata	Data table name. This should have at least the following columns and a variable column to be tested. GRP : Group or Sequence, 'RT' or 'TR' PRD : Period, 1 or 2 SUBJ : Subject ID TRT : Treatment or Drug, 'R' or 'T'
Var	Variable to be estimated. This should be one of the column names in bedata table. Usually 'Tmax'

Details

It nonparametrically tests Var variable equivalency from a 2x2 study. This is done for a variable which we cannot assume log-normal distribution.

Value

Wilcoxon Rank-Sum (Mann-Whitney) Test
Two-sided nonparametric test p-value
Hodges-Lehmann Estimate
90% confidence interval in the original scale and the percent scale

Author(s)

Kyun-Seop Bae <k@acr.kr>

Examples

```
hodges(NCAREsult4BE, "Tmax")
```

mse2cv

Coefficient of variation (CV) from mean squared error (MSE)

Description

It calculates coefficient of variation (CV) from mean squared error (MSE).

Usage

```
mse2cv(mse)
```

Arguments

mse	Mean square error (MSE) in log scale
-----	--------------------------------------

Details

Coefficient of variation (CV) is percent in the original scale and mean squared error (MSE) is the log scale.

Value

Returns coefficient of variation (CV) in percent (%).

Author(s)

Kyun-Seop Bae <k@acr.kr>

Examples

```
mse2cv(0.06062462)
```

NCAResult4BE	<i>An Example of Noncompartmental Analysis Result for Bioequivalence Test</i>
--------------	---

Description

Contains a noncompartmental analysis result table from a concentration simulated bioequivalence study.

Usage

```
NCAResult4BE
```

Format

A data frame with 66 observations on the following 7 variables.

SUBJ Subject ID

GRP Group or Sequence character code: 'RT' or 'TR'

PRD Period numeric value: 1 or 2

TRT Treatment or Drug code: 'R' or 'T'

AUClast AUClast positive numeric value

Cmax Cmax positive numeric value

Tmax Tmax positive numeric value

Details

This contains a simulated data for 2x2 bioequivalence study data analysis. Noncompartmental analysis results are from the NonCompartment package.

plot2x2	<i>Plot bioequivalence variable of a 2x2 study</i>
---------	--

Description

It plots two 2x2 plots for a variable.

Usage

```
plot2x2(bedata, Var)
```

Arguments

bedata	Data table name. This should have at least the following columns and a variable column to be plotted. GRP : Group or Sequence, 'RT' or 'TR' PRD : Period, 1 or 2 SUBJ : Subject ID TRT : Treatment or Drug, 'R' or 'T'
Var	Variable to be plotted. This should be one of the column names in bedata table.

Details

It plots Var column values according to GRP, PRD, TRT.

Value

It just draws two 2x2 plots for equivalence exploration.

Author(s)

Kyun-Seop Bae <k@acr.kr>

Examples

```
plot2x2(NCAREsult4BE, "AUClast")
plot2x2(NCAREsult4BE, "Cmax")
plot2x2(NCAREsult4BE, "Tmax")
```

`pow2x2ci`*Power using a confidence interval of previous 2x2 study*

Description

It calculates power for the bioequivalence test on ratio using a confidence interval of previous 2x2 study.

Usage

```
pow2x2ci(n1, n2, LL, UL, Alpha = 0.1)
```

Arguments

<code>n1</code>	Subject count of group 1
<code>n2</code>	Subject count of group 2
<code>LL</code>	Lower limit of the confidence interval of geometric mean ratio (Test/Reference)
<code>UL</code>	Upper limit of the confidence interval of geometric mean ratio (Test/Reference)
<code>Alpha</code>	Alpha level. This means $(1 - \alpha/2) \times 100$ % confidence interval is given

Details

It calculates power from the confidence interval (LL, UL) of a previous 2x2 study.

Value

Returns power [0, 1)

Author(s)

Kyun-Seop Bae <k@acr.kr>

Examples

```
pow2x2ci(12, 13, 0.85, 1.11)
```

 pow2x2mse

Power using mean squared error (MSE) of previous 2x2 study

Description

It calculates power for the bioequivalence test on ratio using mean squared error (MSE) of previous 2x2 study.

Usage

```
pow2x2mse(n1, n2, mse, True.R = 1, Alpha = 0.1, ThetaL = 0.8, ThetaU = 1.25)
```

Arguments

n1	Subject count of group 1
n2	Subject count of group 2
mse	Mean squared error
True.R	True ratio of test/reference
Alpha	Alpha level. This means $(1 - \alpha/2) \times 100$ % confidence interval is given
ThetaL	Lower limit of equivalence criteria
ThetaU	Upper limit of equivalence criteria

Details

It calculates power of sample size (n per group) with mse.

Value

Returns power [0, 1)

Author(s)

Kyun-Seop Bae <k@acr.kr>

Examples

```
pow2x2mse(12, 13, 0.0756530)
```

powcv

*Power using coefficient of variation (CV)***Description**

It calculates power for the bioequivalence test on ratio using coefficient of variation (CV).

Usage

```
powcv(n, CV, DesignNo = 1, True.R = 1, Alpha = 0.1, ThetaL = 0.8, ThetaU = 1.25)
```

Arguments

n	Sample size, n per group
CV	Coefficient of Variation (%)
DesignNo	Crossover design number. Design Number (treatment x sequence x period) 1 2x2x2 : RT TR 2 2x4x2 (Balaam Design) : TT RR RT TR 3 2x2x3 (Two-sequence Dual Design): TRR RTT 4 2x2x4 : TRRT RTTR 5 2x4x4 : TTRR RRTT TRRT RTTR 6 3x6x3 (William Design for 3 treatments) + carry-over effect : RBA ARB BAR ABR BRA RAB 7 3x6x3 (William Design for 3 treatments) - carry-over effect : RBA ARB BAR ABR BRA RAB 8 4x4x4 (William Design for 4 treatments) + carry-over effect : RCAB ARBC BACR CBRA 9 4x4x4 (William Design for 4 treatments) - carry-over effect : RCAB ARBC BACR CBRA
True.R	True ratio of test/reference
Alpha	Alpha error level
ThetaL	Lower limit of equivalence criteria
ThetaU	Upper limit of equivalence criteria

Details

It calculates power of sample size (n per group) with CV.

Value

Returns power [0, 1)

Author(s)

Kyun-Seop Bae <k@acr.kr>

Examples

```
powcv(12, 25)
```

powmse

Power using mean squared error (MSE)

Description

It calculates power for the bioequivalence test on ratio using mean squared error (MSE).

Usage

```
powmse(n, mse, DesignNo = 1, True.R = 1, Alpha = 0.1, ThetaL = 0.8, ThetaU = 1.25)
```

Arguments

n	Sample size, n per group
mse	Mean squared error
DesignNo	Crossover design number. Design Number (treatment x sequence x period) 1 2x2x2 : RT TR 2 2x4x2 (Balaam Design) : TT RR RT TR 3 2x2x3 (Two-sequence Dual Design): TRR RTT 4 2x2x4 : TRRT RTTR 5 2x4x4 : TTRR RRTT TRRT RTTR 6 3x6x3 (William Design for 3 treatments) + carry-over effect : RBA ARB BAR ABR BRA RAB 7 3x6x3 (William Design for 3 treatments) - carry-over effect : RBA ARB BAR ABR BRA RAB 8 4x4x4 (William Design for 4 treatments) + carry-over effect : RCAB ARBC BACR CBRA 9 4x4x4 (William Design for 4 treatments) - carry-over effect : RCAB ARBC BACR CBRA
True.R	True ratio of test/reference
Alpha	Alpha error level
ThetaL	Lower limit of equivalence criteria
ThetaU	Upper limit of equivalence criteria

Details

It calculates power of sample size (n per group) with mse.

Value

Returns power [0, 1)

Author(s)

Kyun-Seop Bae <k@acr.kr>

Examples

```
pwmse(12, 0.06)
```

scaledBound

Widened Bound for Scaled Average Bioequivalence

Description

It calculates widened bound for scaled average bioequivalence.

Usage

```
scaledBound(CV = 40, k = 0.76, digits = 4)
```

Arguments

CV	coefficient of variation in percent
k	0.76 is for EMA and Korea MFDS. US FDA uses 0.893. When CV is 30%, bound becomes (0.8, 1.25). Most regulatory bodies do not use a more accurate value.
digits	Korea MFDS use 4 digits only, while other regulatory bodies use more decimal values.

Details

CV must be larger than 30%. For EMA and Korea MFDS ($k = 0.76$) the CV is capped at 50% for the widening, while US FDA ($k = 0.893$) is not capped. US FDA uses this widened bound for both AUClast and Cmax, while EU EMA and Korea MFDS use this for Cmax only.

Value

widened bound for scaled average bioequivalence

Author(s)

Kyun-Seop Bae <k@acr.kr>

Examples

```
scaledBound(30)
scaledBound(35)
scaledBound(40)
scaledBound(45)
scaledBound(50)
```

`ss2x2ci`*Sample size using a confidence interval of previous 2x2 study*

Description

It calculates sample size for the bioequivalence test on ratio using a confidence interval of previous 2x2 study.

Usage

```
ss2x2ci(n1, n2, LL, UL, Alpha = 0.1)
```

Arguments

n1	Subject count of group 1
n2	Subject count of group 2
LL	Lower limit of the confidence interval of geometric mean ratio (Test/Reference)
UL	Upper limit of the confidence interval of geometric mean ratio (Test/Reference)
Alpha	Alpha level. This means $(1 - \alpha/2) \times 100$ % confidence interval is given

Details

It calculates sample size (n per group) from the confidence interval (LL, UL) with Alpha for bioequivalence test.

Value

Returns a matrix with the sample size (n per group) and the achieved power (%) at the given n1, n2, each evaluated for True Ratio = 1 and True Ratio = point estimate.

Author(s)

Kyun-Seop Bae <k@acr.kr>

Examples

```
ss2x2ci(12, 13, 0.85, 1.11)
```

SSCV

*Sample size using coefficient of variation (CV)***Description**

It calculates sample size for the bioequivalence test on ratio using coefficient of variation (CV).

Usage

```
sscv(CV, DesignNo = 1, True.R = 1, Alpha = 0.1, Beta = 0.2,
      ThetaL = 0.8, ThetaU = 1.25, nMax = 999999)
```

Arguments

CV	Coefficient of Variation (%)
DesignNo	Crossover design number. Design Number (treatment x sequence x period) 1 2x2x2 : RT TR 2 2x4x2 (Balaam Design) : TT RR RT TR 3 2x2x3 (Two-sequence Dual Design): TRR RTT 4 2x2x4 : TRRT RTTR 5 2x4x4 : TTRR RRTT TRRT RTTR 6 3x6x3 (William Design for 3 treatments) + carry-over effect : RBA ARB BAR ABR BRA RAB 7 3x6x3 (William Design for 3 treatments) - carry-over effect : RBA ARB BAR ABR BRA RAB 8 4x4x4 (William Design for 4 treatments) + carry-over effect : RCAB ARBC BACR CBRA 9 4x4x4 (William Design for 4 treatments) - carry-over effect : RCAB ARBC BACR CBRA
True.R	True ratio of test/reference
Alpha	Alpha error level
Beta	Beta error level
ThetaL	Lower limit of equivalence criteria
ThetaU	Upper limit of equivalence criteria
nMax	Maximum subject number (sample size) per group

Details

It calculates sample size (n per group) with CV, Alpha, and Beta for bioequivalence test.

Value

Returns sample size (n per group) for bioequivalence test with ratio criteria.

Author(s)

Kyun-Seop Bae <k@acr.kr>

Examples

```
sscv(25)
```

ssmse	<i>Sample size using mean squared error (MSE)</i>
-------	---

Description

It calculates sample size for the bioequivalence test on ratio using mean squared error (MSE).

Usage

```
ssmse(mse, DesignNo = 1, True.R = 1, Alpha = 0.1, Beta = 0.2,
      ThetaL = 0.8, ThetaU = 1.25, nMax = 999999)
```

Arguments

mse	Mean squared error
DesignNo	Crossover design number. Design Number (treatment x sequence x period) 1 2x2x2 : RT TR 2 2x4x2 (Balaam Design) : TT RR RT TR 3 2x2x3 (Two-sequence Dual Design): TRR RTT 4 2x2x4 : TRRT RTTR 5 2x4x4 : TTRR RRTT TRRT RTTR 6 3x6x3 (William Design for 3 treatments) + carry-over effect : RBA ARB BAR ABR BRA RAB 7 3x6x3 (William Design for 3 treatments) - carry-over effect : RBA ARB BAR ABR BRA RAB 8 4x4x4 (William Design for 4 treatments) + carry-over effect : RCAB ARBC BACR CBRA 9 4x4x4 (William Design for 4 treatments) - carry-over effect : RCAB ARBC BACR CBRA
True.R	True ratio of test/reference
Alpha	Alpha error level
Beta	Beta error level
ThetaL	Lower limit of equivalence criteria
ThetaU	Upper limit of equivalence criteria
nMax	Maximum subject number (sample size) per group

Details

It calculates sample size (n per group) with mse, Alpha, and Beta for bioequivalence test.

Value

Returns sample size (n per group) for bioequivalence test with ratio criteria.

Author(s)

Kyun-Seop Bae <k@acr.kr>

Examples

```
ssmse(0.06)
```

SSSCV

Sample Size for Scaled Average BE using coefficient of variation (CV)

Description

It calculates sample size for the scaled average bioequivalence test on ratio using coefficient of variation (CV).

Usage

```
ssscv(CV, DesignNo = 1, True.R = 1, Alpha = 0.1, Beta = 0.2, Region = "EU", nMax = 999999)
```

Arguments

CV	Coefficient of Variation (%)
DesignNo	Crossover design number.
	Design Number (treatment x sequence x period)
	1 2x2x2 : RT TR
	2 2x4x2 (Balaam Design) : TT RR RT TR
	3 2x2x3 (Two-sequence Dual Design): TRR RTT
	4 2x2x4 : TRRT RTTR
	5 2x4x4 : TTRR RRTT TRRT RTTR
	6 3x6x3 (William Design for 3 treatments) + carry-over effect
	: RBA ARB BAR ABR BRA RAB
	7 3x6x3 (William Design for 3 treatments) - carry-over effect
	: RBA ARB BAR ABR BRA RAB
	8 4x4x4 (William Design for 4 treatments) + carry-over effect
	: RCAB ARBC BACR CBRA
	9 4x4x4 (William Design for 4 treatments) - carry-over effect
	: RCAB ARBC BACR CBRA
True.R	True ratio of test/reference

Alpha	Alpha error level
Beta	Beta error level
Region	US or FDA for US FDA, KR or MFDS for Korea MFDS, EU or EMA for other regions or countries
nMax	Maximum subject number (sample size) per group

Details

It calculates sample size (n per group) with CV, Alpha, and Beta for scaled average bioequivalence test. US FDA uses this widened bound for both AUClast and Cmax, while EU EMA and Korea MFDA use this for Cmax only.

Value

Returns sample size (n per group) for scaled average bioequivalence test with ratio criteria.

Author(s)

Kyun-Seop Bae <k@acr.kr>

Examples

```
ssscv(42.2, DesignNo=4, True.R=0.9) # 14 per group, EU EMA. This applies only for Cmax
ssscv(42.2, DesignNo=4, True.R=0.9, Region="US") # 9 per group, US FDA
ssscv(42.2, DesignNo=4, True.R=0.9, Region="KR") # 14 per group, Korea MFDS. Only for Cmax
```

test2x2	<i>Bioequivalence test for a variable of a 2x2 study</i>
---------	--

Description

It performs conventional bioequivalence test for 2x2 study. Basic assumption is that the variable is distributed as a log-normal distribution. This is SAS PROC GLM style. If you want PROC MIXED style use nlme::lme.

Usage

```
test2x2(bedata, Var)
```

Arguments

bedata	Data table name. This should have at least the following columns and a variable column to be tested. Var column values should be all positive values. GRP : Group or Sequence, 'RT' or 'TR' PRD : Period, 1 or 2 SUBJ : Subject ID TRT : Treatment or Drug, 'R' or 'T'
Var	Variable to be tested. This should be one of the column names in bedata table. Usually 'AUClast' or 'Cmax'

Details

It tests Var variable equivalency from a 2x2 study. Current regulatory requirement is that the 90% confidence interval of geometric mean ratio (Test/Reference) should be within [0.8, 1.25].

The model is $\log(\text{Var}) \sim \text{GRP}/\text{SUBJ} + \text{PRD} + \text{TRT}$, and it is fitted with the **sasLM** package. The analysis of variance uses Type III sums of squares from [T3test](#), where GROUP (sequence) is tested against SUBJECT(GROUP) and every other term against the residual mean square, as SAS PROC GLM with a RANDOM statement does. The geometric least square means come from [LSM](#) and the confidence interval from [CIest](#).

Value

Analysis of Variance (log scale)

Analysis of Variance in log scale, with the columns Df, Sum Sq, Mean Sq, F value, and Pr(>F)

Between and Within Subject Variability

Variance in log scale and coefficient of variance in original scale

Least Square Means (geometric mean)

Geometric means

90% Confidence Interval of Geometric Mean Ratio (T/R)

90% confidence interval of geometric mean ratio (T/R)

Sample Size

Sample size for the replication of this study

Author(s)

Kyun-Seop Bae <k@acr.kr>

See Also

[T3test](#), [LSM](#), [CIest](#)

Examples

```
test2x2(NCAResult4BE, "AUClast")
test2x2(NCAResult4BE, "Cmax")
```

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