

Package: ssPilot (via r-universe)

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Type Package

Title Sample Size Calculation for External Pilot Studies for a Continuous Endpoint

Version 1.0.0.9000

Description An implementation of sample size calculations for external pilot studies that minimize the overall trial sample size for the external pilot and main trial for a continuous endpoint as described in Whitehead et al. (2016)
<doi:10.1177/0962280215588241>.

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URL <https://github.com/joeldadiboe-rgb/ssPilot>

BugReports <https://github.com/joeldadiboe-rgb/ssPilot/issues>

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nct_sample_size	<i>Main trial sample size using the non-central t-distribution</i>
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Description

Calculates the required main-trial sample size per treatment arm using the non-central t-distribution (NCT) approach described by Julious and Owen.

Usage

```
nct_sample_size(  
  pilot_n,  
  sd,  
  effect,  
  power = 0.9,  
  alpha = 0.05,  
  allocation = 1,  
  max_n = 10000  
)
```

Arguments

pilot_n	Pilot trial sample size per treatment arm.
sd	Pilot estimate of the standard deviation.
effect	Expected treatment difference.
power	Desired statistical power.
alpha	Type I error rate.
allocation	Allocation ratio of experimental to control arm.
max_n	Maximum main-trial sample size per arm to search.

Details

See also `ssPilot::optimized_nct_sample_size`.

Value

A list containing the pilot-trial sample size per arm, pilot-trial degrees of freedom, required main-trial sample size per arm, main-trial degrees of freedom, central t critical value, non-central t quantile, and the right-hand side of Equation (4).

References

Julious SA and Owen RJ. Sample size calculations for clinical studies allowing for uncertainty about the variance. *Pharmaceut Stat* 2006; 5: 29–37.

Examples

```
nct_sample_size(
  pilot_n = 12,
  sd = 1,
  effect = 0.50,
  power = 0.90,
  alpha = 0.05
)
```

optimized_nct_sample_size

Optimize pilot sample size using the non-central t-distribution

Description

Determines the pilot-trial sample size per treatment arm that minimizes the total sample size required for the pilot and main trials using the non-central t-distribution (NCT) approach.

Usage

```
optimized_nct_sample_size(
  sd,
  effect,
  power = 0.9,
  alpha = 0.05,
  allocation = 1,
  min_pilot_n = 10,
  max_pilot_n = 100,
  max_main_n = 10000
)
```

Arguments

sd	Anticipated standard deviation based on prior knowledge, previous studies, published literature, or other available evidence.
effect	Expected treatment difference.
power	Desired statistical power.
alpha	Type I error rate.
allocation	Allocation ratio of experimental to control arm.
min_pilot_n	Minimum pilot sample size per treatment arm.
max_pilot_n	Maximum pilot sample size per treatment arm.
max_main_n	Maximum main-trial sample size per treatment arm passed to [nct_sample_size()].

Details

The function evaluates a range of possible pilot sample sizes and calls `[nct_sample_size()]` for each candidate pilot size. The optimal pilot sample size is the one that minimizes the combined pilot and main-trial sample size per arm.

Value

A list containing:

- optimal_pilot_n_per_arm** Optimal pilot sample size per arm.
- main_n_per_arm** Required main-trial sample size per arm corresponding to the optimal pilot size.
- total_n_per_arm** Combined pilot and main-trial sample size per arm.
- pilot_degrees_of_freedom** Degrees of freedom from the pilot trial.
- main_degrees_of_freedom** Degrees of freedom from the main trial.
- critical_value** Critical value from the corresponding main-trial calculation.
- nct_quantile** Non-central t quantile from the corresponding calculation.
- equation_value** Sample-size equation value from the corresponding calculation.
- optimization_results** Data frame containing the results for all candidate pilot sample sizes.

References

Whitehead, A. L., Julious, S. A., Cooper, C. L., & Campbell, M. J. (2016). Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Statistical Methods in Medical Research*, 25(3), 1057–1073.

Examples

```
results <- optimized_nct_sample_size(
  sd = 1,
  effect = 0.50,
  power = 0.90,
  alpha = 0.05
)
plot(results)
```

optimized_ucl_sample_size

Optimized pilot sample size using the UCL method

Description

Finds the pilot-trial sample size per treatment arm that minimizes the combined pilot and main-trial sample size using the upper confidence limit approach.

Usage

```
optimized_ucl_sample_size(  
  sd,  
  effect,  
  power = 0.9,  
  alpha = 0.05,  
  allocation = 1,  
  conf_level = 0.8,  
  min_pilot = 10,  
  max_pilot = 100  
)
```

Arguments

sd	Anticipated standard deviation based on prior knowledge, previous studies, published literature, or other available evidence.
effect	Expected treatment difference.
power	Desired statistical power for the main trial.
alpha	Type I error rate.
allocation	Allocation ratio of experimental to control arm.
conf_level	Confidence level for the upper confidence limit.
min_pilot	Minimum pilot sample size per treatment arm.
max_pilot	Maximum pilot sample size per treatment arm to search.

Value

A list containing the optimal pilot sample size per arm, the corresponding main-trial sample size per arm, the total sample size per arm, the confidence level used, and a data frame containing the optimization results for all candidate pilot sample sizes.

References

Whitehead, A. L., Julious, S. A., Cooper, C. L., & Campbell, M. J. (2016). Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Statistical Methods in Medical Research*, 25(3), 1057–1073.

Examples

```
results <- optimized_ucl_sample_size(  
  sd = 1,  
  effect = 0.50,  
  power = 0.90,  
  alpha = 0.05,  
  conf_level = 0.80  
)  
plot(results)
```

plot.sspilot	<i>Plot pilot and main-trial sample size relationship</i>
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Description

Creates a plot showing the relationship between pilot-trial sample size and the corresponding main-trial sample size from an optimized sample size calculation. The combination that minimizes the total sample size is highlighted.

Usage

```
## S3 method for class 'sspilot'
plot(x, ...)
```

Arguments

x	A data frame containing the optimization results. It must contain columns named 'pilot_n_per_arm', 'main_n_per_arm', and 'total_n_per_arm'.
...	Additional arguments to be passed to methods.

Value

A ggplot object showing pilot-trial sample size against main-trial sample size, with the optimal combination highlighted.

Examples

```
ucl_results <- optimized_ucl_sample_size(
  sd = 1,
  effect = 0.50,
  power = 0.90,
  alpha = 0.05
)

plot(ucl_results)
```

standard_sample_size	<i>Standard sample size for a two-arm continuous outcome trial</i>
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Description

Calculates the required main-trial sample size per treatment arm assuming the population standard deviation is known.

Usage

```
standard_sample_size(sd, effect, power = 0.9, alpha = 0.05, allocation = 1)
```

Arguments

sd	Population standard deviation.
effect	Expected treatment difference.
power	Desired statistical power.
alpha	Type I error rate.
allocation	Allocation ratio of experimental to control arm.

Value

Required sample size per treatment arm.

Examples

```
standard_sample_size(  
  sd = 1,  
  effect = 0.5,  
  power = 0.90,  
  alpha = 0.05  
)
```

ucl_sample_size	<i>Main trial sample size using the upper confidence limit method</i>
-----------------	---

Description

Calculates the required main-trial sample size per treatment arm using the upper confidence limit (UCL) approach described by Browne.

Usage

```
ucl_sample_size(  
  pilot_n,  
  sd,  
  effect,  
  power = 0.9,  
  alpha = 0.05,  
  allocation = 1,  
  conf_level = 0.8  
)
```

Arguments

<code>pilot_n</code>	Pilot trial sample size per treatment arm.
<code>sd</code>	Pilot estimate of the standard deviation.
<code>effect</code>	Expected treatment difference.
<code>power</code>	Desired statistical power.
<code>alpha</code>	Type I error rate.
<code>allocation</code>	Allocation ratio of experimental to control arm.
<code>conf_level</code>	Confidence level for the upper confidence limit.

Details

Browne recommends an 80 level. However, Sim and Lewis, set X at 0.95 or the 95

Value

A list containing the degrees of freedom, upper confidence limit for the variance, upper confidence limit for the standard deviation, and main-trial sample size per treatment arm.

References

Browne RH. On the use of a pilot sample for sample size determination. *Stat Med* 1995; 14: 1933–1940.

Sim J and Lewis M. The size of a pilot study for a clinical should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol* 2012; 65: 301–308.

Examples

```
ucl_sample_size(
  pilot_n = 16,
  sd = 1,
  effect = 0.50,
  power = 0.90,
  alpha = 0.05,
  conf_level = 0.80
)
```

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