



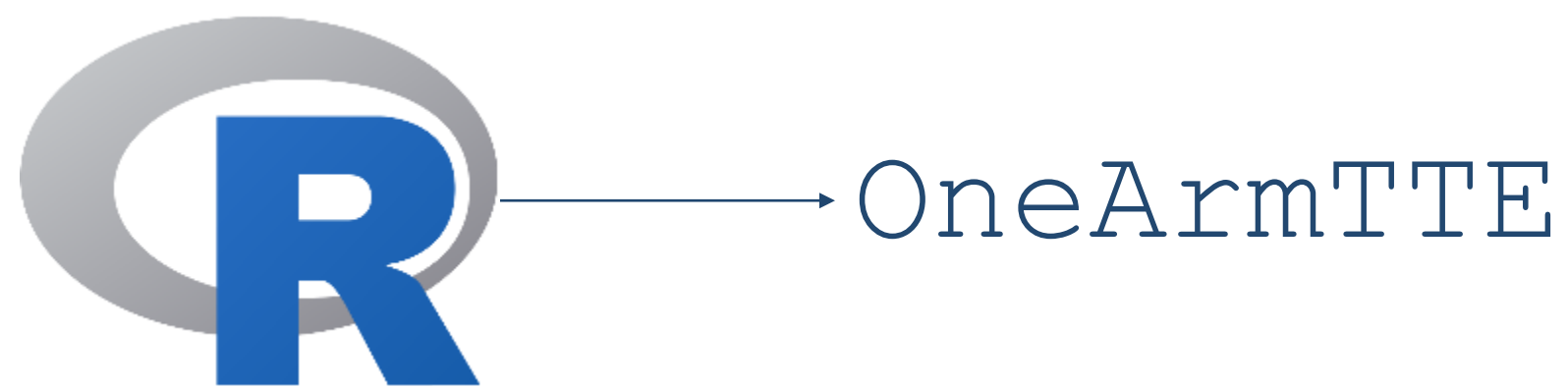
One sample Log-Rank test for one sample survival studies: SAS code vs R code

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Why implementing the OneSample Log Rank test in SAS?

- One arm trials are common in phase II studies
- It makes possible a comparison between observed data and an historic control with only the median known
- R software has specific libraries to handle the OneSample Log Rank like OneArmTTE, while SAS has no specific PROCs



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Method: statistical principles

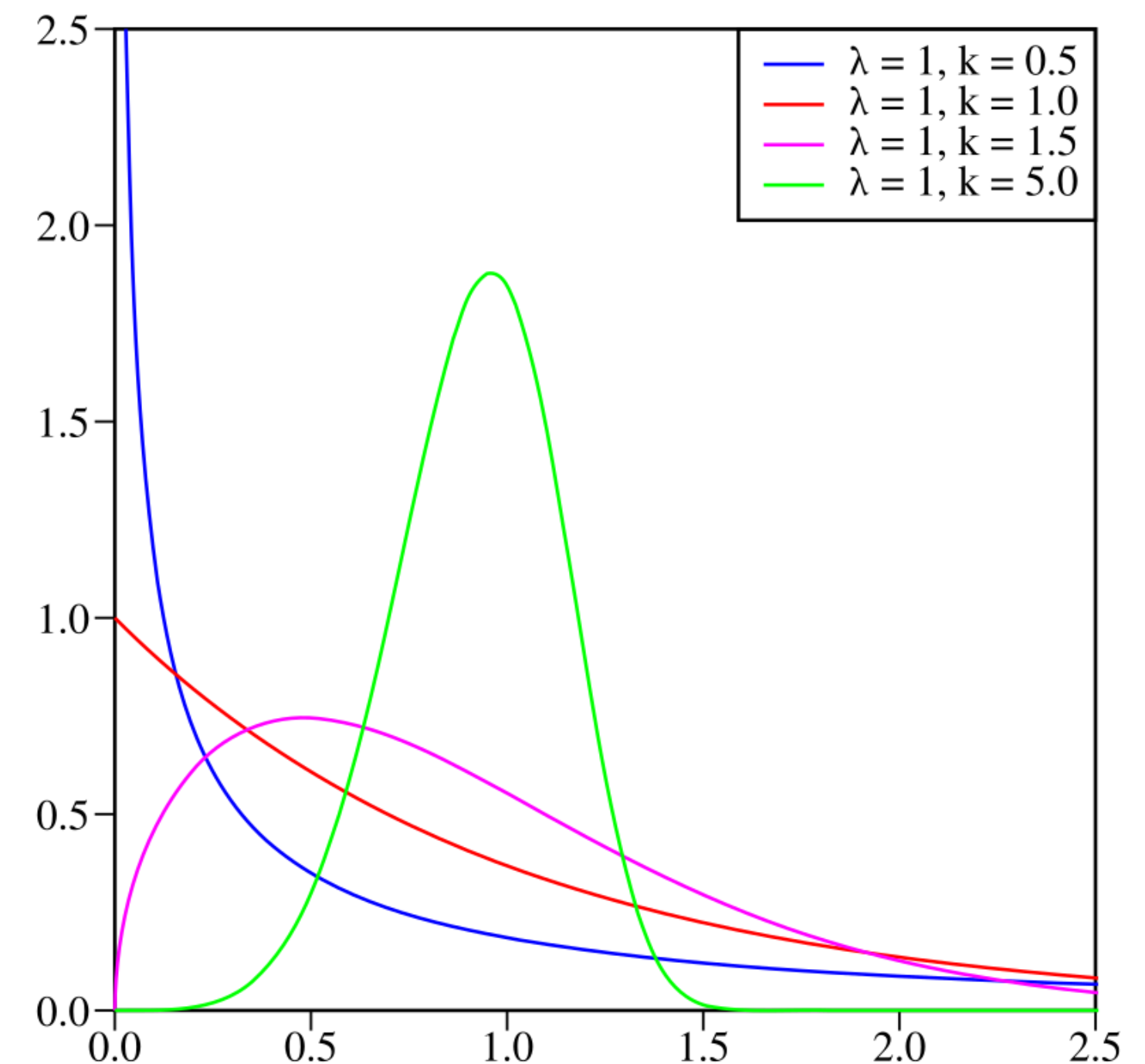
- Hypothesis: Weibull distribution of the time to event data, considering the following parameters
 - k , the shape parameter
 - Me , the median used as historic control
 - λ , the scale parameter, calculated as function of k and Me

$$\lambda = \frac{Me}{\sqrt[k]{\ln 2}}$$

- Z test statistic calculated as:

$$Z = \frac{O - E}{\sqrt{E}}$$

Where O are the observed events and E the expected ones



Method: statistical principles

- Calculation of E , the number of expected events:
 Assuming a Weibull distribution, the survival function $S(t_i)$ is equal to

$$S(t_i) = \exp \left\{ - \left(\frac{t_i}{\lambda} \right)^k \right\}$$

Remembering that $\lambda = \frac{Me}{\sqrt[k]{\ln 2}}$, we obtain that

$$S(t_i) = \exp \left\{ - \left(\frac{t_i}{\lambda} \right)^k \right\} = \exp \left\{ - \left(\frac{t_i}{\frac{Me}{\sqrt[k]{\ln 2}}} \right)^k \right\} = \exp \left\{ - \frac{t_i^k * \ln 2}{Me^k} \right\}$$

The Hazard function $H(t_i)$ is defined as $-\ln(S(t_i))$, so

$$H(t_i) = -\ln \left[\exp \left\{ - \frac{t_i^k * \ln 2}{Me^k} \right\} \right] = - \left(- \frac{t_i^k * \ln 2}{Me^k} \right) = \frac{t_i^k * \ln 2}{Me^k}$$

The Expected events are $E = \sum_{i=1}^n H(t_i)$, so it can be concluded that

$$E = \sum_{i=1}^n \frac{t_i^k * \ln 2}{Me^k} = \frac{\ln 2}{Me^k} \sum_{i=1}^n t_i^k$$

The most common case is $k = 1$, that implies

$$E = \frac{\ln 2}{Me} \sum_{i=1}^n t_i$$

SAS Code

Considering a dataset `pop` containing the observed data with variable `time` about the time to event and censored, a dummy variable for each subject indicating if it showed the event or not, we can obtain the test statistic and the pvalue as shown below

```
data dataset1; set pop;
status=(censored=0);
time=time**&shape.;
run;

ods output Summary=sums1;
proc means data=dataset1 sum; var time status; run;

data sums2; set sums1;
observed=status_sum;
expected=time_sum*log(2)/&median.**&shape.;
Z=abs((observed-expected)/expected**,5);
pvalue=2*(1-PROBNORM(Z));
run;
```

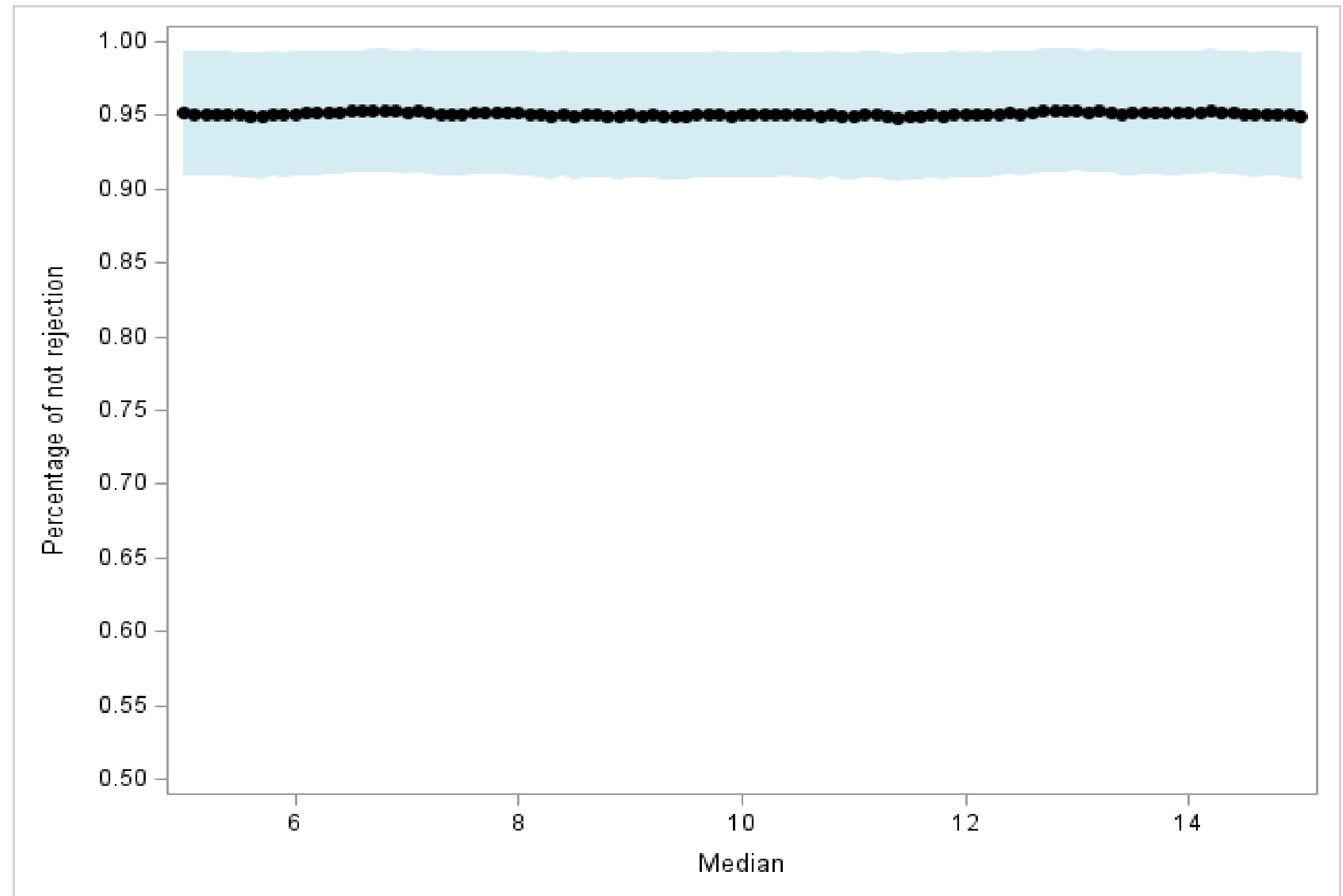
Method Validation

First simulation

We created a simulated dataset considering:

- 150 patient for cohort
- Different values of the median from 5 to 15
- 10,000 simulations for each different median
- The null hypothesis of historic control median equal to the one of the observed data as true
- $\alpha = 0,05$ as significance threshold

We obtained as expected that 95% of scenarios not rejected the null hypothesis. This result is stable regardless of the median of reference.



Method Validation

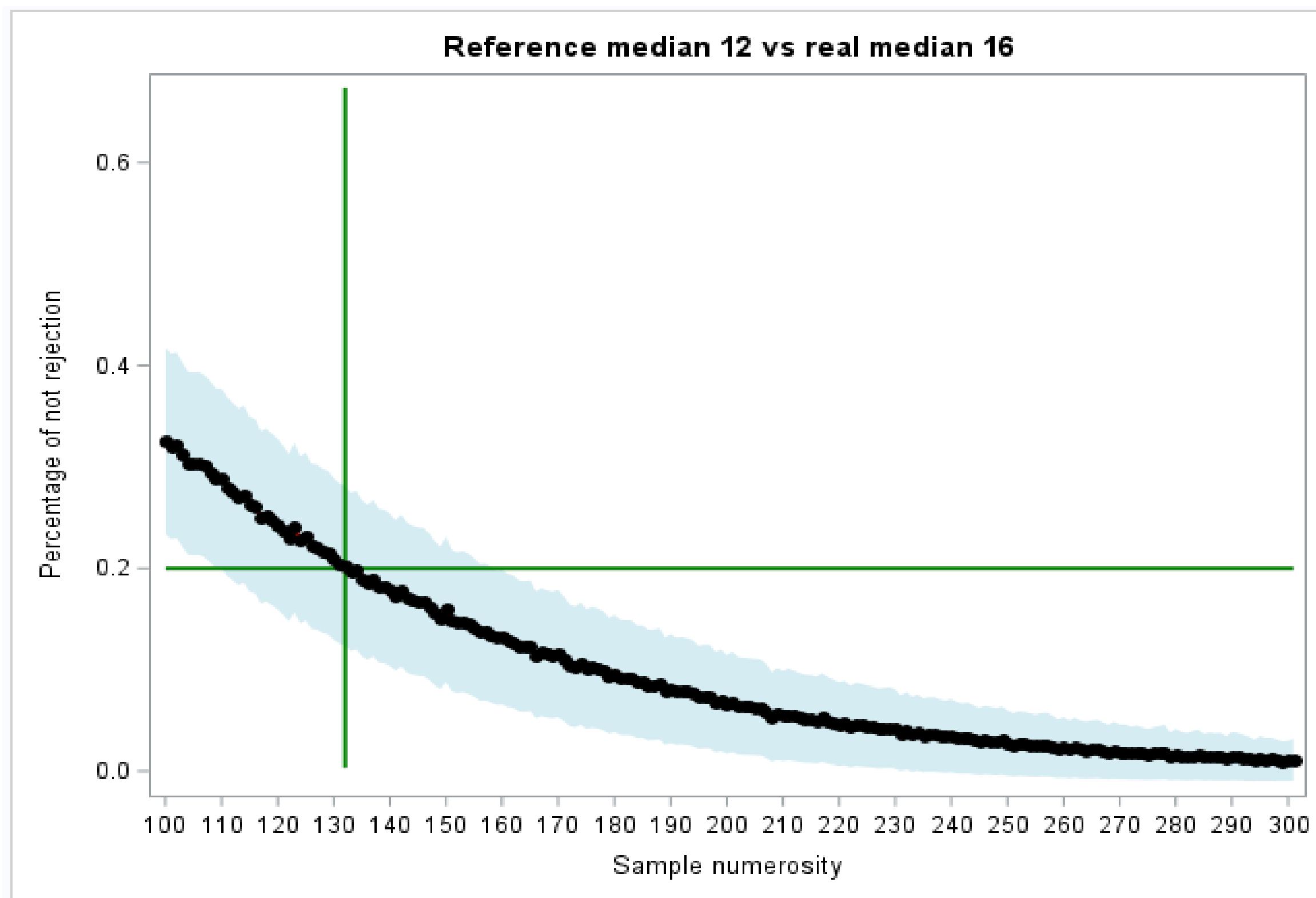
Second simulation

We created a simulated dataset considering:

- $\alpha = 0,05$ as significance threshold
- Historic control median equal to 12
- True median equal to 16
- Different sample numerosity from 100 to 300 patients
- 10,000 simulations for each sample numerosity

We assumed a power equal to 80% and calculated the sample size using PASS, obtaining 132 patients.

The graph shows that the results obtained with SAS are consistent with PASS's ones, with 20% of probability of incorrect non rejection when the null hypothesis is wrong with sample size equal to 132



Conclusions

- The illustrated method can implement the OneSample Log Rank as PASS or R
- It can be applied in phase II studies with survival endpoints, both to estimate the sample size and to estimate the probability that the observed data comes from a specific value for the median
- It can implement scenarios with any shape parameter k , while OneArmTTE considers only the case when $k=1$

Contacts

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