Documentation for Running the Programs Described in "Calculating the Power or Sample size for the Logistic and Proportional Hazards Model's"

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1 What is in the Software Distribution

The distribution includes an application `Logistic_Cox_Power.exe` which displays a window that allows the user to obtain the power or the sample size for the Cox and Logistic models. The window is an interface to two MATLAB programs that perform the calculation without MATLAB installed. If you have MATLAB, the m-files are in the directory where the application is installed labeled "Logistic_Cox_power_mcr".

2 Using the Software

The application has text boxes for each of the parameters of subroutines. The first four parameters of the Cox program (powc9.m) are unique to the Cox model, the remaining parameters are common to both the Cox model and the Logistic model (powl8.m).

All the parameters are either numbers or MATLAB matrices which are entered enclosed in square brackets "[ ]", rows are separated by a ";" and row elements are separated by spaces. For instance the matrix with first row 1,2 and second row 3,4 is denoted by "[1 2;3 4]". Any MATLAB statements, using built in MATLAB functions, that resolve to a matrix are allowable as parameters
(see http://www.mathworks.com/access/helpdesk/help/techdoc/math/math.html).

The application is pre-populated with an example to show how it might be used. The following table describes the parameters.

Table 1: Model Parameters

Name	Size	Description
Cox Model only		
acr	number	Patient accrual period, you can use any unit you wish but shorter units will give a more accurate power estimate
fup	number	Follow up period in same units as accrual period
drop	number	Rate that patients drop out of study per unit above, i.e. If drop=0.05 then 5% of the patients that are on study will drop out in each of the `acr + fup` intervals. This is in addition to the attrition due to patients reaching the end of the study. Patients who drop out are considered to be censored at the time of drop out.
h	fup+acr $\times$ 1	Underlying hazard function for each interval
Both Models		
wt	$K \times 1$	The proportion of subjects in each group that has the same discrete covariates $w_1, \ldots, w_K$ in section 2 of the paper.

Table 2: Model Parameters, continued

xd	$K \times q$	The discrete covariate values for each group above, the rows of the matrix are are $v_1, \ldots, v_k$ in section 2. The cox model should not include a constant covariate while the logistic model usually will.
xc	$K \times r$	The means for continuous covariates for each group above, the rows of the matrix are $\mu_1, \ldots$ in section 2.
var	$K \times r(r+1)/2$	Each row is the upper triangle of the variance covariance matrix for the continuous covariates for the corresponding group.
b	$(q+r) \times 1$	The value of the parameter vector under H_a
b0	$(q+r) \times 1$	The value of the parameter vector under H_0
a	$(q+r) \times \rho$	Contrast matrix for tests to be performed, A in section 4
cTotalN	number	Sample size, if zero the sample size will be calculated
pow	number	Power, if zero and cTotalN>0 then power will be calculated. If both cTotalN and Power are both greater than zero and a $\rho = 1$ then a multiplier will be calculated for the alternative hypothesis that gives the specified power at the specified sample size. If otherwise, an error is returned using a negative value.
alpha	number	Significance level.
sides	number	Either 1 or 2 depending on whether a one sided or two sided test is desired

3 Example-Logistic Regression

The application is pre-populated with an example, which represents a call to the powl8 if the logistic button is pushed. The parameters are separated by ",".

```
y=powl8([.5;.5],[1 0;1 1],[0;0],[1;1],[0; log(2); 0],...
[0;0;0],[0;1;0],0,0.80,0.05,1);
```

The first parameter, wt, indicates that there are two treatment groups each with 50of the patients. The second parameter, xd, is the coding of these two groups. Since a constant term is necessary for the logistic model two discrete covariates are required. The third parameter, xc=[0;0], is the vector of means of the one continuous covariate which has mean zero. Since there is only one continuous covariate the variance covariance matrix of each covariate is simply a constant so the forth parameter is [1;1]. If there were two continuous covariates and they were multivariate normal with unit variances and correlation coeficient equal to 0.5 then the parameter forth parameter, var, would be [1 0.5 1;1 0.5 1]. The alternative hypothesis is that the parameter vector is [0;log(2);0] and the null is that it is [0;0;0]. This implies that the odds ratio due to treatment group would be 2 and the response rate in group 1 would be 0.50 and the response rate in group 2 would be 0.67. The value of the test contrast is [0;1;0] which means we testing for a treatment effect. The sample size is set to 0, the power to 0.80, the significance level to 0.05 and we desire a one sided test.

4 Example-Cox Model

The application is pre-populated with an example which represents a call to the powc9 if the logistic button is pushed. The parameters are separated by ",".

```
y=powc9(24,12,0.0,.3*ones(36,1),[.5;.5],[1 0;1 1],[0;0],[1;1],...
[0; log(2); 0],[0;0;0],[0;1;0],0,0.80,0.05,1);
```

In this example we assume a 24 month accrual period when patients enter the study and a 12 month follow up period for all patients. This implies that the censoring distribution has a uniform distribution between 12 and 36 months. The drop out parameter is zero. and the underlying hazard function is .3*ones(36,1) or [.3; ...;.3] which is exponential with a hazard rate of 0.3.

Note that in this example there is a constant covariate. This is not necessary in the Cox Model. One would get the same answer with

```
y=powc9(24,12,0.0,.3*ones(36,1),[.5;.5],[0;1],[0;0],[1;1],...
[log(2); 0],[0;0],[1;0],0,0.80,0.05,1);
```