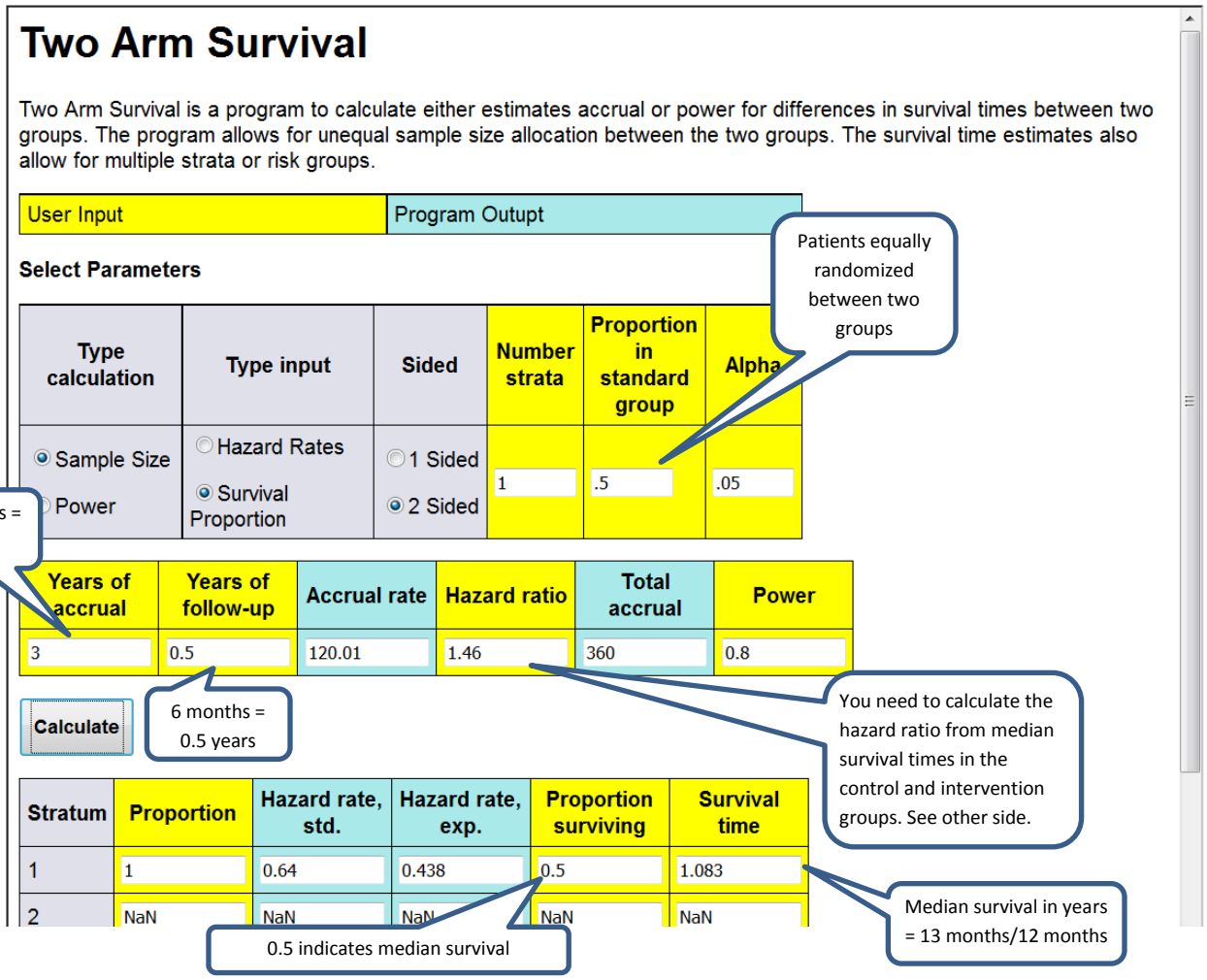
Two-Sample Survival Test

Objective: Compare survival between two groups of independent samples.

A researcher wants to determine if surgery followed by systemic therapy increases survival over systemic surgery alone for patients with colorectal cancer. Study participants will be equally randomized between the treatment groups. The median survival of patients receiving systemic therapy alone is 13 months. The investigator believes that increasing median survival by at least 6 months is necessary to justify surgery. Patients will be recruited over 3 years (36 months) with at least 6 months of follow up.

Required Information	Inputs
What is the desired power for the test?	80%
At what significance level do you want to test your hypothesis?	5%
What is median survival in the control group?	13 months
What difference in median survival do you want to detect?	6 months
For how long do you plan to recruit patients?	36 months
For how long after the last recruitment will you follow patients?	6 months
Is your hypothesis one-sided or two-sided?	Two-sided
What proportion of your sample will be controls?	0.5



A total sample size of at least 360 is necessary, meaning 180 participants in each group.

Example using the Southwest Oncology Group's Statistical Tools (https://stattools.crab.org/)

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Converting among survival parameters

Commonly survival times are assumed to follow an exponential distribution. With this assumption, converting between median survival times and hazard rates is easily accomplished with the following formulas.

The hazard rate (λ) is the number of events per unit time. Assuming an exponential distribution, the median survival time is related to the rate by the following formula:

$$Median\ survival\ time = log_e(2)/\lambda$$

Thus, the hazard rate can be calculated from median survival time as

$$\lambda = log_e(2)/Median\ survival$$

In our example, the control group has median survival in years of 1.083 (13 months/12 months) which using the above formula, yields a hazard rate of λ_C = 0.64. We want to detect an increase of 6 months in survival (i.e., 19 months/12 months). This yields a hazard rate of λ_I = 0.438. The desired detectable hazard ratio is 0.64/0.438 = 1.46. The Southwest Oncology sample size calculator requires the hazard ratio to be > 1; thus, we divide 0.64 by 0.438.

Example using the Southwest Oncology Group's Statistical Tools (https://stattools.crab.org/)