

# Predictive Probabilities User's Guide

## Version 1.5

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March 19, 2014

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# Chapter 1

## Binary outcomes

### 1.1 Statistical model

Suppose you have interim data from a randomized two-arm experiment with a binary outcome, and the following data have been observed:

	Treatments	
	A	B
# Successes	$X_A$	$X_B$
# Failures	$m_A - X_A$	$m_B - X_B$
Success Probability	$\theta_A$	$\theta_B$

Assume a priori  $\theta_A$  and  $\theta_B$  are independently distributed as  $\text{beta}(a, b)$ . Assume also that

$$X_A | \theta_A \sim \text{binomial}(\theta_A, m_A)$$

and

$$X_B | \theta_B \sim \text{binomial}(\theta_B, m_B).$$

These assumptions imply that, a posteriori,

$$\theta_A | X_A \sim \text{beta}(a + X_A, b + m_A - X_A)$$

and

$$\theta_B | X_B \sim \text{beta}(a + X_B, b + m_B - X_B).$$

Denote the future data by the following table:

	Treatments	
	A	B
# Successes	$Y_A$	$Y_B$
# Failures	$n_A - Y_A$	$n_B - Y_B$

At the end of the experiment, the total number of observations on arm A will be

$$N_A = m_A + n_A$$

and the total number of patients on arm B will be

$$N_B = m_B + n_B.$$

The values  $N_A$  and  $N_B$  are the planned total samples sizes. Now

$$\begin{aligned} P(Y_A = y | X_A) &= \int_0^1 P(Y_A = y | \theta) P(\theta | X_A) d\theta \\ &= \binom{n_A}{y} \frac{B(a + X_A + y, b + m_A - X_A + n_A - y)}{B(a + X_A, b + m_A - X_A)} \end{aligned}$$

where  $P(Y_A = y | \theta)$  denotes the binomial probability distribution for the future data and

$$B(\alpha, \beta) = \frac{\Gamma(\alpha)\Gamma(\beta)}{\Gamma(\alpha + \beta)}.$$

### 1.1.1 Frequentist approach

The usual frequentist estimates of  $\theta_A$  and  $\theta_B$  and the overall  $\theta$  if  $\theta_A = \theta_B$  are

$$\begin{aligned} \hat{\theta}_A &= \frac{Y_A + X_A}{N_A}, \\ \hat{\theta}_B &= \frac{Y_B + X_B}{N_B}, \\ \hat{\theta} &= \frac{Y_A + X_A + Y_B + X_B}{N_A + N_B}. \end{aligned}$$

The usual frequentist two-sample statistic for testing equality of two proportions is

$$Z = \frac{\hat{\theta}_A - \hat{\theta}_B}{\sqrt{\hat{\theta}(1 - \hat{\theta}) \frac{N_A + N_B}{N_A N_B}}}.$$

The test rejects  $H_0: \theta_A = \theta_B$  if  $|Z| > z_{1-\alpha^*/2}$  where  $\alpha^*$  is the significance level of the test.

The *predictive probability* of this test rejecting, given the interim data, is

$$\sum_{y_A, y_B} P(Y_A = y_A | X_A) P(Y_B = y_B | X_B) [|Z| > z_{1-\alpha^*/2}]$$

where  $[\cdot]$  is the indicator function that returns 1 if the Boolean expression inside is true and 0 otherwise.

The expression

$$[|Z| > z_{1-\alpha^*/2}]$$

requires some explanation. For a given  $(y_A, y_B)$  term in the sum, calculate the z-score of the data at the end of the trial if there are  $y_A$  additional successes out of  $n_A$  additional patients on A and  $y_B$  additional successes on B out of  $n_B$  additional patients on B. That would be a total of  $x_A + y_A$  successes out of  $m_A + n_A$  patients on A and  $x_B + y_B$  successes out of  $m_B + n_B$  patients on B. If that z-score is above the critical value, the indicator function evaluates to 1, and so that term is included in the sum. Otherwise the expression evaluates to zero, removing that term from the sum.

Using this idea, the program returns two predictive probabilities. The first is the predictive probability that the test will conclude  $\theta_A > \theta_B$  and the second is the predictive probability that the test will conclude  $\theta_B > \theta_A$ . These are calculated by replacing  $[|Z| > z_{1-\alpha^*/2}]$  with  $[Z > z_{1-\alpha^*/2}]$  and  $[Z < z_{\alpha^*/2}]$ , respectively. Note that in general these two probabilities do not sum to 1 because there is the possibility that the trial will be inconclusive.

Note that what we are calling a “frequentist” approach here is a sort of hybrid. We are computing the *Bayesian* predictive probability of a *frequentist* test passing.

### 1.1.2 Bayesian approach

A Bayesian approach calculates the probability  $P(\theta_A > \theta_B | \text{data})$  by determining what the posterior would be for a given set of data. That is,

$$P(\theta_A > \theta_B | \text{data}) = \int_0^1 P(\theta_B | Y_B) \int_{\theta_B}^1 P(\theta_A | Y_A) d\theta_A d\theta_B.$$

The *predictive probability* of this test rejecting, given the interim data, is

$$\sum_{y_A, y_B} P(Y_A = y_A | X_A) P(Y_B = y_B | X_B) [P(\theta_A > \theta_B | \text{data}) > c]$$

Typical values of  $c$  would be 0.90 or 0.95 depending on how certain you need to be that  $\theta_A > \theta_B$ . The program returns two predictive probabilities. The first is the predictive probability that the test will conclude  $\theta_A > \theta_B$  and the second is the predictive probability that the test will conclude  $\theta_B > \theta_A$ . As with the frequentist approach, in general these two probabilities do not sum to 1 because there is the possibility that the trial will be inconclusive.

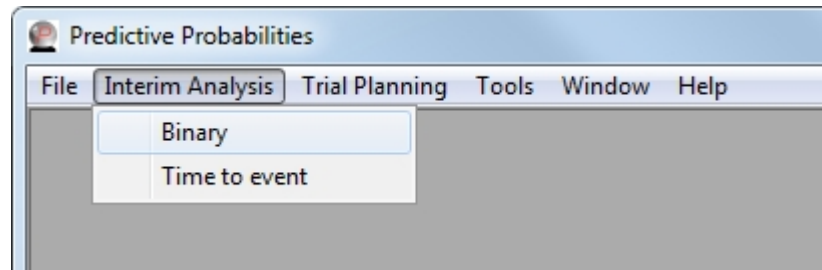


Figure 1.1: Starting a binary interim analysis

## 1.2 Interim analysis

The most common use of this software is performing an interim analysis of a clinical trial. This is useful, for example, when determining whether a trial should continue to enroll patients. This functionality can be accessed by going to the Interim Analysis menu as shown in Figure 1.1.

This will bring up the main form for this method as shown in Figure 1.2

The Results tab, circled in red in Figure 1.3, will contain the table for the most recent calculations.

The History tab, circled in red in Figure 1.4, will contain all of the calculations conducted during this session. This tab allows you to save the output as an HTML file.

### 1.2.1 Entering current data

For binary data, the current data section of the user interface is shown in Figure 1.5

The “# of Success” is the current number of patients that have had a “success” according to the protocol definition and “# of Failures” is the corresponding number of non-successes. The totals will automatically be updated as you enter data.

If you have no current data, try using the trial planning functionality described in Section 1.3.

### 1.2.2 Specifying priors

The prior parameters are entered into the portion of the user interface shown in Figure 1.6.

Typically, the prior parameters are chosen so that the prior mean,  $E(\pi_i) = \alpha/(\alpha + b)$ , is set to the historical probability of success. The parameter  $\alpha$  can

Predictive Probabilities - Binary Data

Setup Results History

Current Data

	Treatment A	Treatment B	Total
# of Successes	<input type="text"/>	<input type="text"/>	0
# of Failures	<input type="text"/>	<input type="text"/>	0
Total	0	0	0

Prior

Denote the probability of success of treatment  $i$  by  $\pi_i$

$\pi_i \sim \text{Beta}(a_i, b_i)$

	Treatment A	Treatment B
a	<input type="text"/>	<input type="text"/>
b	<input type="text"/>	<input type="text"/>

Additional Information

The planned total number of patients on Treatment A.

The planned total number of patients on Treatment B.

Significance for two-sided frequentist test [\(details\)](#)

Bayesian inequality probability  $\Pr(\pi_i > \pi_j + \delta)$  [\(details\)](#)

Delta term in the above inequality

Calculate

Figure 1.2: Main form for binary interim analysis

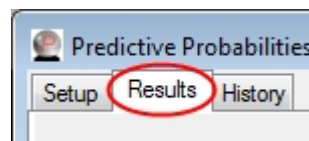


Figure 1.3: Results tab

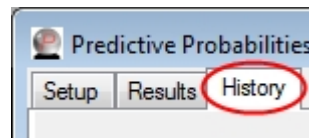


Figure 1.4: History tab



Current Data

	Treatment A	Treatment B	Total
# of Successes	<input type="text" value="0"/>	<input type="text" value="0"/>	0
# of Failures	<input type="text" value="0"/>	<input type="text" value="0"/>	0
Total	0	0	0

Figure 1.5: Current data

Prior

Denote the probability of success of treatment  $i$  by  $\pi_i$

$\pi_i \sim \text{Beta}(a_i, b_i)$

	Treatment A	Treatment B
a	<input type="text" value="1"/>	<input type="text" value="1"/>
b	<input type="text" value="1"/>	<input type="text" value="1"/>

Figure 1.6: Prior parameters

Additional Information	
The planned total number of patients on Treatment A.	<input type="text"/>
The planned total number of patients on Treatment B.	<input type="text"/>
Significance for two-sided frequentist test <a href="#">(details)</a>	0.05
Bayesian inequality probability $\Pr(\pi_i > \pi_j + \text{delta})$ <a href="#">(details)</a>	0.975
Delta term in the above inequality	0

Figure 1.7: Additional information

be interpreted as the prior number of success and  $b$  can be interpreted as the prior number of patient failures.

For convenience, a Parameter Solver utility has been provided to aid in specifying the prior. By right-clicking on either “Treatment A” or “Treatment B” you will get a menu which will activate the Parameter Solver. You may use the Parameter Solver to determine the priors for that arm based and export these values to the prior parameter fields. See Section 3.3.

### 1.2.3 Additional information

This section refers to the following portion of the user interface for interim analysis of binary trials as shown in Figure 1.7.

“The planned number of patients on treatment A” is the number of patients that one expects to have been assigned treatment A at the end of patient accrual. This must be at least as large as the current number of patients on treatment A. Similar remarks apply to treatment B.

If the planned number of patients on both A and B are equal to the current quantity of patients, the predictive probability will return either 1 or 0, depending on the value of  $P(\pi_i > \pi_j | \text{data})$ .

See Section 1.1 for a discussion of the Bayesian and frequentist methods of analyzing the trial. In practice, the methods often give very similar results.

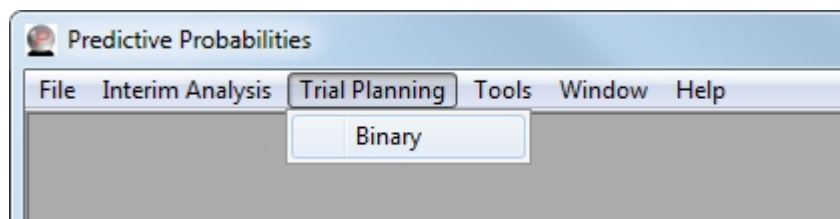


Figure 1.8: Starting trial planning from menu

### 1.3 Trial planning

You can access the trial planning functionality by clicking on the Trial Planning menu at the top of the application and selecting Binary as shown in Figure 1.8. (At this point, the trial planning functionality is only available for the binary model.)

This brings up the main form for the method, shown in Figure 1.9.

This method is used for planning a trial using predictive probabilities. It assumes that you will enroll a specified number of patients on arm A and B, and then would like to check the predictive probability of concluding one arm is superior. For example, suppose you plan to enroll 10 patients in each treatment. Then the possible outcomes are 0, 1,  $\dots$ , 10 successes on each treatment. The output will be a table indexed by all possible outcomes in the first stage. The values in the table will consist of the predictive probability of selecting a treatment as superior given the various outcomes in the first stage. You may specify the range of values that appear in the output table by selecting a “minimum number of success” and “maximum number of success” to be different than 0 and the number of patients enrolled in the first stage, respectively.

After entering all data and selecting a method for comparison, click the Calculate button. The prior and statistical model for this version corresponds to the interim analysis for binary data.

The Results and History tabs work as described above in Section 1.2.

**Predictive Probabilities - Binary outcome, trial planning**

Setup Results History

**Setup**

How many patients will you enroll on Treatment A before looking?

For Treatment A the minimum number of success you want the table to list is?

For Treatment A the maximum number of success you want the table to list is?

How many patients will you enroll total on Treatment A?

How many patients will you enroll on Treatment B before looking?

For Treatment B the minimum number of success you want the table to list is?

For Treatment B the maximum number of success you want the table to list is?

How many patients will you enroll total on Treatment B?

**Prior**

Denote the probability of success of treatment  $i$  by  $\pi_i$

$\pi_i \sim \text{Beta}(a_i, b_i)$

	Treatment A	Treatment B
a	<input type="text"/>	<input type="text"/>
b	<input type="text"/>	<input type="text"/>

**Calculation Method**

When deciding if two proportions are equal what method would you like to use?

Significance for two-sided frequentist test [\(details\)](#)

Bayesian inequality probability  $\Pr(\pi_i > \pi_j + \text{delta})$  [\(details\)](#)

Delta term in the above inequality

Calculate

Figure 1.9: Main trial planning form

## Chapter 2

# Time-to-event outcomes

### 2.1 Statistical model

Suppose that you have interim data from a randomized two-arm experiment with a time-to-event outcome, comparing treatments A and B. We assume that the “event” is undesirable (such as disease progression or death) and so one wants to maximize the time to the event, or equivalently that one wants to minimize the rate of the event.

Assume the following data have been observed:

	Treatments	
	A	B
Number of patients	$N_A$	$N_B$
Number of patients with outcome observed	$M_A$	$M_B$
Total exposure time	$E_A$	$E_B$
Rate	$\lambda_A$	$\lambda_B$

Given patient  $k$  receives treatment  $j$ , with  $j$  equal to A or B, denote the observed event time by  $X_{k,j}$ . We assume that  $X_{k,j}$  is exponentially distributed with mean  $\mu_j$  and we assume a priori that  $\mu_j$  is distributed as an inverse gamma with shape parameter  $\alpha_j$  and scale parameter  $\beta_j$ . We abbreviate this as  $IG(\alpha_j, \beta_j)$ . See Section 3.1 for more details regarding the inverse gamma distribution.

When specifying the prior,  $\alpha_j$  can be thought of as the prior number of events on arm  $j$  and  $\beta_j$  can be thought of as the prior exposure time.

Given the current data for treatment  $j$  as denoted in the table above, the posterior distribution on  $\mu_j$  is  $IG(\alpha_j + M_j, \beta_j + E_j)$ . At the next evaluation a

decision must be made about which treatment is the better. If

$$P(\mu_A > \mu_B | \text{data}) > P_U,$$

for example one may have chosen  $P_U = 0.95$ , then arm A would be selected as superior, and similarly for treatment B. In order to predict how likely it is that this condition will be met at the next evaluation, the remainder of the trial is simulated. The simulation is carried out as follows:

1. Set  $\rho_j = 0$  for  $j = A, B$ . These are counters for the number of significant tests in favor of A over B or B over A.
2.  $m_j$  is simulated from the posterior of each treatment.
3. Patients are randomly assigned to one of the treatments and their event times are simulated from the corresponding distribution.
4. When the end of the trial is reached and additional follow-up is completed, the event time of any patient who has not had his/her event observed is treated as censored.
5. Denote the data at the end of the trial for arm  $j$  by  $\text{data}_{F,j}$ , which consists of the current data and the simulated future data on arm  $j$ .
6. If  $P(\mu_A > \mu_B | \text{data}_{F,A}, \text{data}_{F,B}) > P_U$  then increment  $\rho_A$  by 1 and similarly for arm B.
7. Repeat steps 2 - 6 for the specified number of replications  $n$ .
8. The predictive probability of declaring arm A as superior is  $\rho_A/n$  and for arm B is  $\rho_B/n$ .

The frequentist variation uses the same procedure as the Bayesian model except that the test at the end of the simulated trial is based on the usual frequentist normal approximation. Specifically, at the end of the each simulated trial, we conclude that arm A has a lower hazard than arm B if

$$\frac{\lambda_A - \lambda_B}{\sqrt{\lambda_A/E_A + \lambda_B/E_B}} < Z_\alpha$$

and conclude that arm B has a lower hazard rate arm A if

$$\frac{\lambda_A - \lambda_B}{\sqrt{\lambda_A/E_A + \lambda_B/E_B}} > -Z_\alpha$$

where  $Z_\alpha = \Phi^{-1}(\alpha)$  and  $\Phi$  is the CDF of the standard normal distribution.

As with the binary model, what we are calling “frequentist” here is not strictly a frequentist approach. We are computing the (Bayesian) predictive probability of passing a frequentist test.

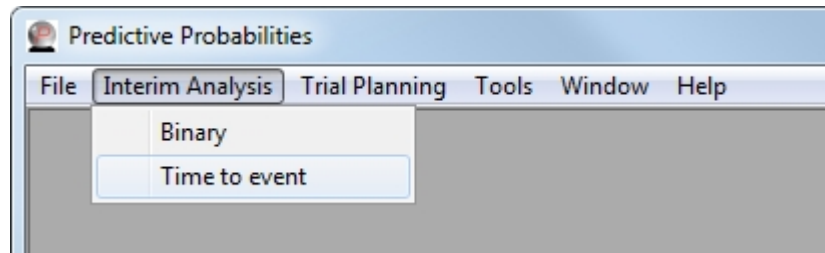


Figure 2.1: Starting a time-to-event interim analysis

## 2.2 Interim analysis

To begin an interim analysis of a time-to-event trial, select time to event from the Interim Analysis menu as shown in Figure 2.1.

This will bring up the dialog shown in Figure 2.2.

The Results and History tabs work as described above in Section 1.2.

### 2.2.1 Entering current data

The current data is entered into a portion of the user interface shown in Figure 2.3.

The following example will help illustrate how to determine the inputs.

Suppose for Arm A you have 3 patients.

1. A patient who has been observed for 2 months with no event.
2. A patient who was observed for 3.5 months and then had the event.
3. A patient who has been observed for 1 month with no event.

The number of patients is obviously 3. The number of events is 1. The total exposure time is  $2 + 3.5 + 1 = 6.5$ .

### 2.2.2 Additional data

The additional data section of the user interface is shown in Figure 2.4.

The anticipated number of patients accrued each month is needed for simulation purposes. Patients are assumed to arrive according to a Poisson process with this rate.

After accrual is complete there is typically a period of follow-up to allow the data to “mature” before making a decision.

The software asks how long have patients been accruing in order to determine how long the trial will continue if the maximum duration option is selected.

**Predictive Probabilities - Time-To-Event**

Setup Results History

**Current Data**

	Treatment A	Treatment B
Number of patients	<input type="text"/>	<input type="text"/>
Number of events	<input type="text"/>	<input type="text"/>
Total exposure time (in months)	<input type="text"/>	<input type="text"/>

**Additional Data**

Anticipated number of patients accrued each month

Additional follow-up after accrual has stopped (in months)

Accrual will terminate when

Please check at least one

☐ A maximum patient accrual has been reached

☐ A maximum duration has been reached (in months)

How long have patients been accruing (in months)

☐ A maximum number of events has occurred

**Method of Comparison**

Compare Posteriors Frequentist Test

This method is based on the following model:

$X_{i,1}, X_{i,2}, \dots, X_{i,n} \sim i.i.d \text{ Exponential}(\text{mean} = \mu_i)$

$\mu_i \sim \text{Inverse Gamma}(a, b_i); E(\mu_i) = b_i / (a - 1)$ ; with shape parameter  $a$  and scale parameter  $b_i$ . At the next evaluation a decision must be made about which treatment is the better. If  $\Pr(\mu_i > \mu_j | \text{Data}) > P_U$ , for example  $P_U = 0.95$ , then arm  $i$  would be selected as superior. In order to predict how likely it is that this condition will be met at the next evaluation, the remainder of the trial will be simulated.

**Prior Parameters**

	Treatment A	Treatment B
shape	<input type="text"/>	<input type="text"/>
scale	<input type="text"/>	<input type="text"/>

How many times would you like to simulate the remainder of the trial?

At the next evaluation conclude arm  $i$  is better than arm  $j$  if  $\Pr(\mu_i > \mu_j | \text{Data}) >$

Figure 2.2: Main form for time-to-event

**Current Data**

	Treatment A	Treatment B
Number of patients	<input type="text"/>	<input type="text"/>
Number of events	<input type="text"/>	<input type="text"/>
Total exposure time (in months)	<input type="text"/>	<input type="text"/>

Figure 2.3: Entering current data



Additional Data

Anticipated number of patients accrued each month

Additional follow-up after accrual has stopped (in months)

Accrual will terminate when

Please check at least one

☐ A maximum patient accrual has been reached

☐ A maximum duration has been reached (in months)

How long have patients been accruing (in months)

☐ A maximum number of events has occurred

Figure 2.4: Entering additional information

Accrual will terminate when

Please check at least one

☐ A maximum patient accrual has been reached

☐ A maximum duration has been reached (in months)

How long have patients been accruing (in months)

☐ A maximum number of events has occurred

Figure 2.5: Accrual termination

### 2.2.3 Accrual termination

The accrual termination section of the user interface is shown in Figure 2.5.

In order to determine when the trial will end you must select at least one of the three options:

- **A maximum patient accrual has been reached** This includes the current patients and therefore must be larger than the current number of patients in the trial.
- **A maximum trial duration (in months)** This is the total length of the trial. This number must be larger than the length of time patients have been accruing. For example, if patients have been accruing for 6 months and you enter 7, this means there will only be 1 month of additional accrual.
- **A maximum number of events have occurred** This is the total number of events in the trial. It must be greater than the current number of events in the trial.

## 2.3 Methods of comparison

See Section 2.1 for more information regarding the Bayesian method of comparison using posterior distributions and the frequentist method.

## Chapter 3

# Miscellaneous topics

### 3.1 Inverse gamma distribution

Let  $\alpha > 0$  be the shape parameter and  $\beta > 0$  the scale parameter. Then the inverse gamma distribution has PDF

$$\left( \frac{\beta^\alpha}{x^{\alpha+1} \Gamma(\alpha)} \right) e^{-\beta/x}$$

for all positive  $x$ .

If  $\alpha > 1$  the mean is

$$\frac{\beta}{\alpha - 1}.$$

If  $\alpha > 2$  the variance is

$$\frac{\beta^2}{(\alpha - 1)^2 (\alpha - 2)}.$$

If  $X$  is distributed as a gamma distribution with parameters  $(\alpha, \beta)$  then  $1/X$  is distributed as an inverse gamma with parameters  $(\alpha, 1/\beta)$ .

NB: The  $\beta$  in our parameterization of the inverse gamma corresponds to  $1/\beta$  in another common convention.

### 3.2 Input validation

If you see a flashing red dot with an exclamation point beside a field, the corresponding input is invalid. Holding your mouse over the dot will display a small message explaining the input assumption that was violated, as shown in Figure 3.1.

If you find yourself unable to enter data or obtain results, look for a red dot with an exclamation point. Note that it may be on a different window.

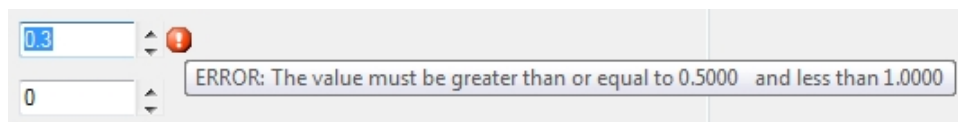


Figure 3.1: Example error indication

### 3.3 Parameter Solver

The Parameter Solver is a utility that will determine the distribution parameters of a random variable given either two quantiles or a specified mean and variance.

The figure above shows the Parameter Solver for the binary case where the prior follows a beta distribution. For changing the graphic options please see Section 3.5 below.

The Parameter Solver is also available as a stand-alone program which supports more distribution families than just the beta and inverse gamma families used in this application. For more information, see

<https://biostatistics.mdanderson.org/SoftwareDownload/>

### 3.4 Inequality Calculator

The Inequality Calculator is a utility to compute the probability that a sample from one random variable is greater than a sample from another. It is accessed either by clicking on the Tools menu then clicking on Inequality Calculator or by right clicking on any prior distribution and then clicking on Inequality Calculator.

As with the Parameter Solver, a more general Inequality Calculator is available as a stand-alone program at

<https://biostatistics.mdanderson.org/SoftwareDownload/>

### 3.5 Graphic options

With any graph there a few options you are able to change. These include:

- X axis minimum and maximum,
- Y axis minimum and maximum,
- X label,
- Y label, and
- title.

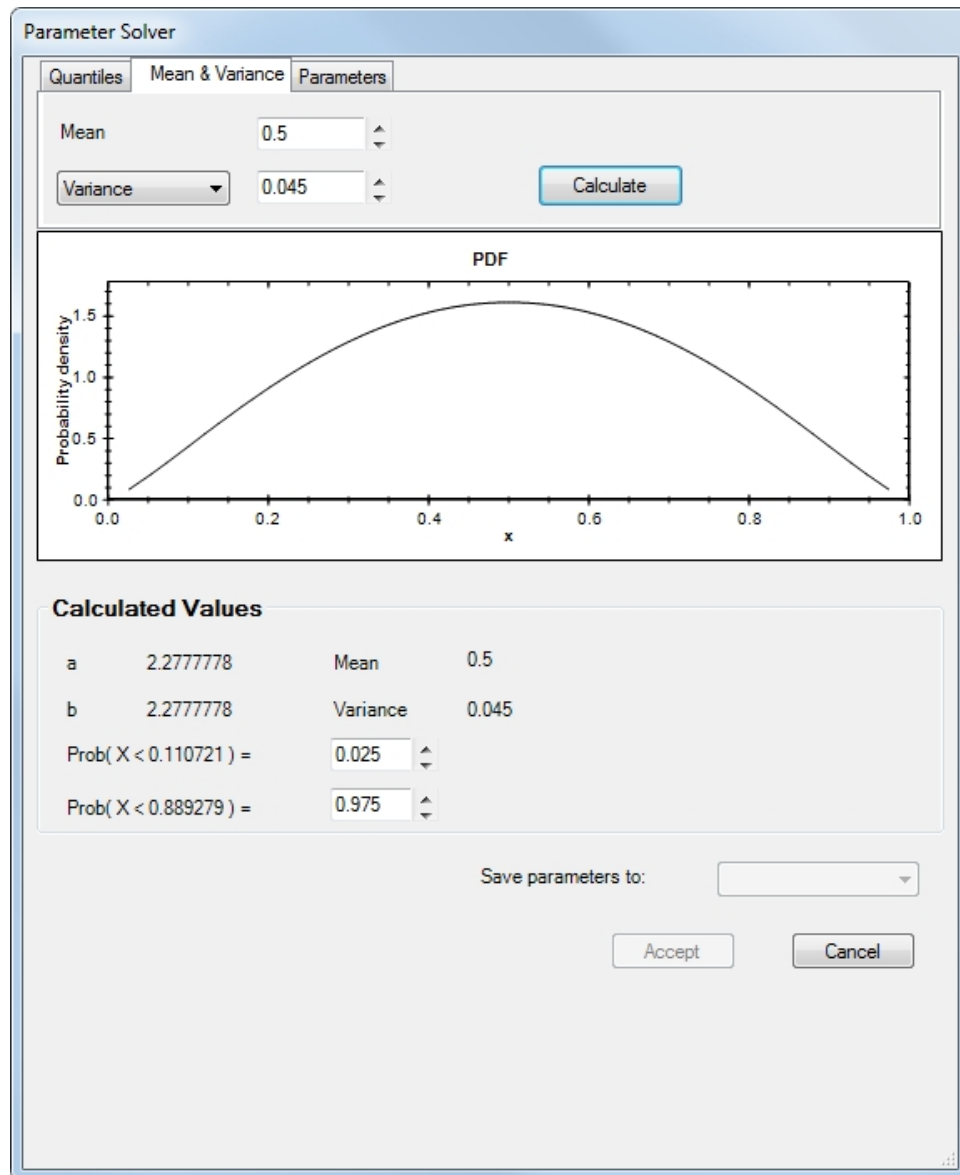


Figure 3.2: Example of using Parameter Solver

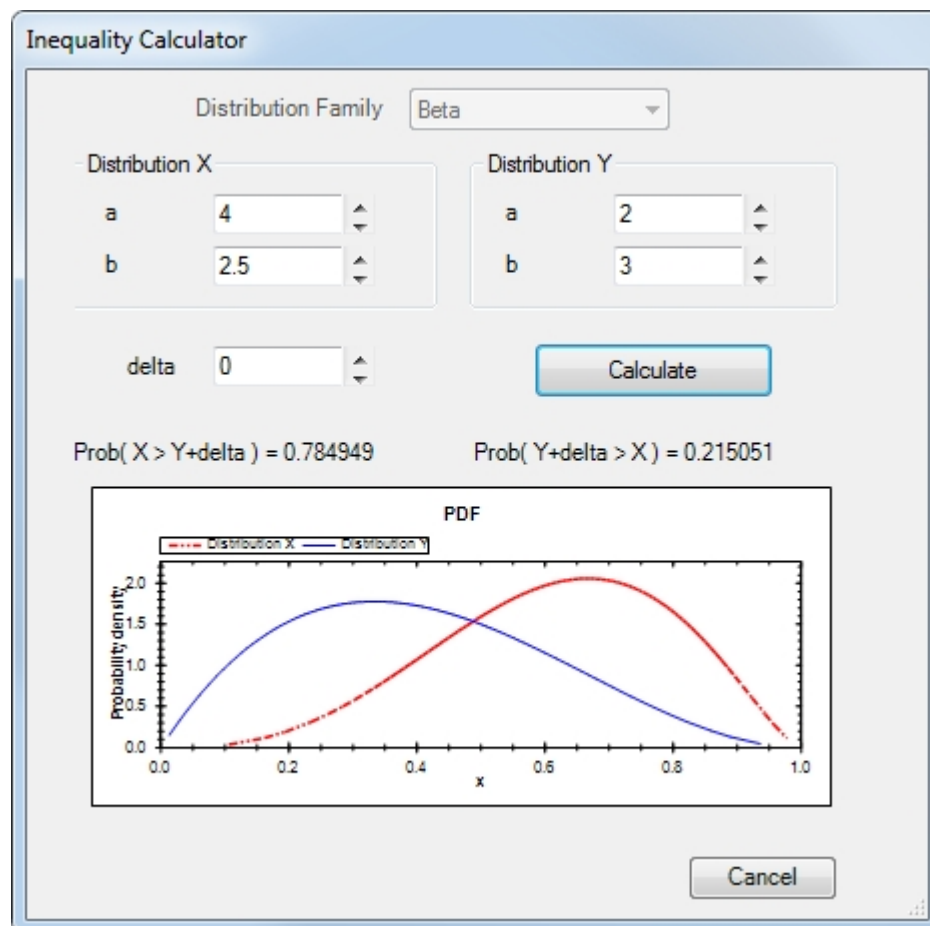


Figure 3.3: Example of using Inequality Calculator

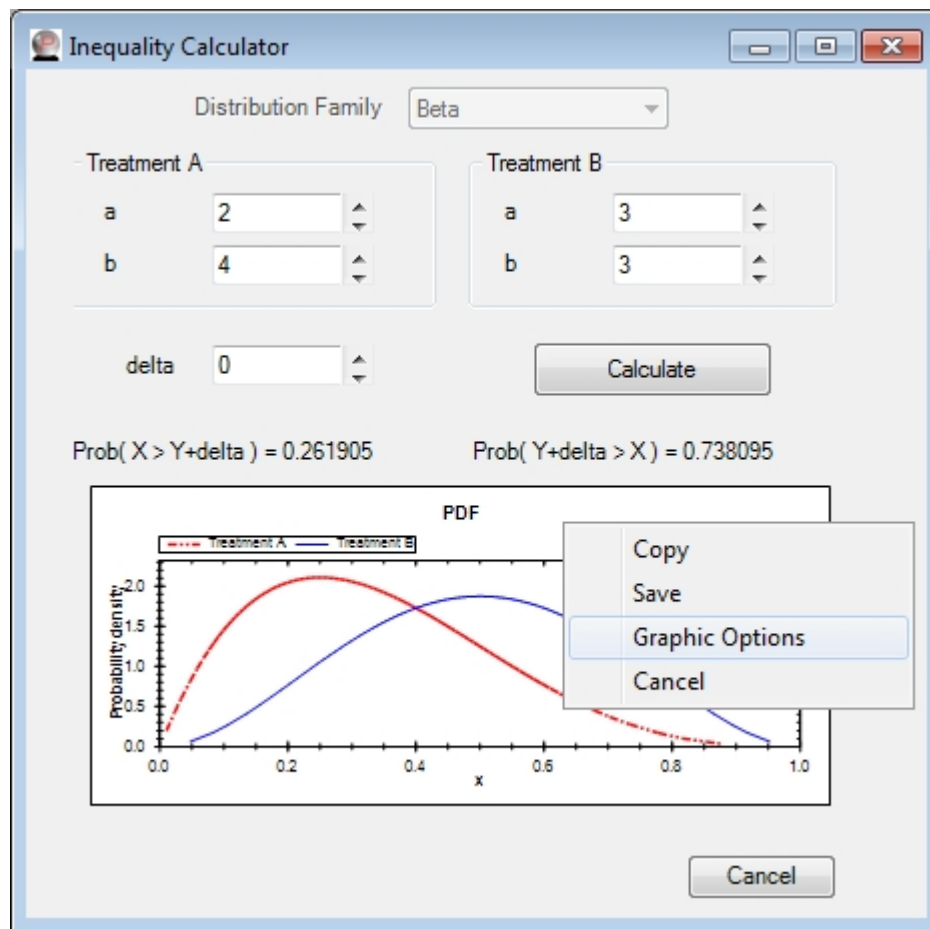


Figure 3.4: Selecting graphic options in the Inequality Calculator

Right-clicking on the graph will display a menu with “Graphic Options” as shown in Figure 3.4.

If you click on “Graphic Options” you will see the dialog in Figure 3.5.

Changes to the graphic options are automatically reflected in the graph pane. If you click “Accept” on the Graphic Options dialog the changes will be saved to the graph. If you click “Cancel” all changes to the graph options will be discarded.

Graphic Options

	X Range	Y Range
Maximum	1	2.320269
Minimum	0	0
Graph Title	PDF	
X - Axis Label	x	
Y - Axis Label	Probability density	

Accept Cancel

Figure 3.5: Graphic options