# 2-Arm, Single Endpoint - Simulate Patient Dropout

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These examples are related to the Integration Point: Dropout. Click here for more information about this integration point.

### Introduction

The following examples illustrate how to customize the dropout distribution in East Horizon or East using R functions. Patients may drop out of a trial for various reasons, including safety concerns, treatment burden, or non-trial-related factors. In some cases, dropout rates can reach 30%, particularly if the drug has adverse side effects. Incorporating dropout probabilities or hazard rates is crucial during data generation and can significantly impact subsequent analysis. In all examples, we assume a trial design consisting of a control group and an experimental treatment.

Once CyneRgy is installed, you can load this example in RStudio with the following commands:

```
CyneRgy::RunExample( "2ArmPatientDropout" )
```

Running the command above will load the RStudio project in RStudio.

**RStudio Project File**: 2ArmPatientDropout.Rproj

In the R directory of this example you will find the following R files:

1. GenerateCensoringUsingBinomialProportion.R - Contains a function named *GenerateCensoringUsingBinomialProportion* to demonstrate the R code necessary for Example 1 as described below.
2. GenerateDropoutTimeForSurvival.R - Contains a function named *GenerateDropoutTimeForSurvival* to demonstrate the R code necessary for Example 2 as described below.
3. GenerateDropoutTimeForRM - Contains a function named *GenerateDropoutTimeForRM* to demonstrate the R code necessary for Example 3 as described below.

## Example 1 - Dropout Using Binomial Proportion

This example is related to this R file: GenerateCensoringUsingBinomialProportion.R.R

The R function *GenerateCensoringUsingBinomialProportion* generates the censoring indicator using the dropout probability specified in East Horizon (*ProbDrop* in the script, *Probability of Dropout* in East Horizon) for continuous or binary outcome. This function applies the binomial distribution to determine dropout status. In this case, the dropout probability is the same across both treatment groups, but this can be customized using user-defined parameters.

This function does not use any user-defined parameters, but uses parameters specified in East Horizon. Refer to the table below for more information.

| Name of the parameter in East Horizon | Where to find the parameter in East Horizon | Name of the variable in the R script |
|---|---|---|
| Probability of Dropout | Response Card | *ProbDrop* |

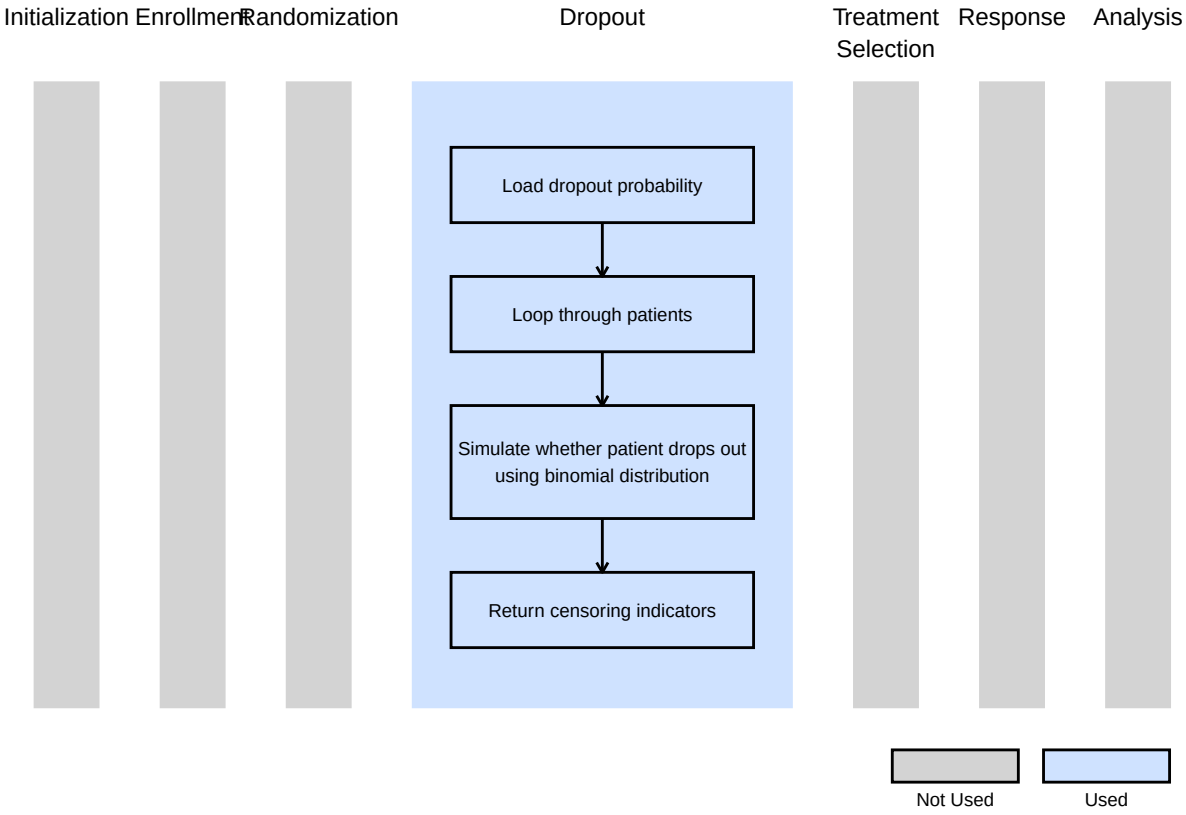
Steps:

1. Let $pd$ be the dropout probability.

2. Draw a random sample from a Bernoulli distribution with $p = 1 - pd$, i.e., $Binomial(1, pd)$, of size $n = NumSub$.

3. The generated sample serves as a censoring indicator:
   - **1** indicates a patient who completes the trial (does not drop out).
   - **0** indicates a patient who drops out (non-completer).

The figure below illustrates where this example fits within the R integration points of Cytel products, accompanied by a flowchart outlining the general steps performed by the R code.




## Example 2 - Dropout Time For Survival

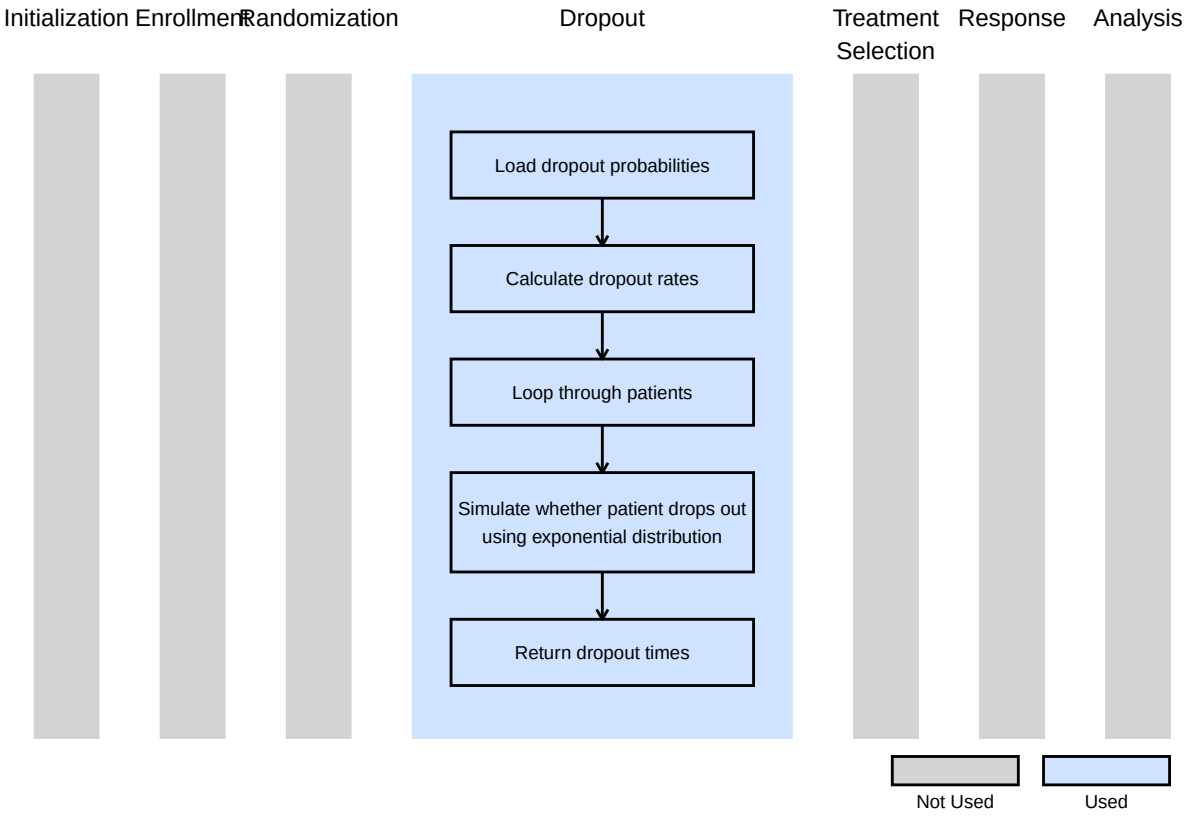
This example is related to this R file: GenerateDropoutTimeForSurvival.R

The function *GenerateDropoutTimeForSurvival* generates dropout times for a two-arm survival design. In this case, dropout information can be specified separately for each arm (in East Horizon, *Control* and *Treatment* in the *Dropout Rate* tab), and dropout times are drawn from an exponential distribution accordingly. The number of periods is fixed at 1.

This function does not use any user-defined parameters, but uses parameters specified in East Horizon. Refer to the table below for more information.

| **Name of the parameter in East Horizon** | **Where to find the parameter in East Horizon** | **Name of the variable in the R script** |
|---|---|---|
| Probability of Dropout: Control | Response Card, Dropout Rate tab | $DropParam[1]$ |
| Probability of Dropout: Treatment | Response Card, Dropout Rate tab | $DropParam[2]$ |

The figure below illustrates where this example fits within the R integration points of Cytel products, accompanied by a flowchart outlining the general steps performed by the R code.




## Example 3 - Dropout Time for Repeated Measures

This example is related to this R file: GenerateDropoutTimeForRM.R

The function *GenerateDropoutTimeForRM* generates dropout times for a continuous outcome with repeated measures design. In this case, dropout information can be specified separately for each arm (in East Horizon, *Control* and *Treatment* in the *Dropout Rate* tab), and dropout times are drawn from an exponential distribution accordingly. The *Input Method* in East Horizon has to be set to *Cumulative Probability of Dropout by Time*.

This function does not use any user-defined parameters, but uses parameters specified in East Horizon. Refer to the table below for more information.

| **Name of the parameter in East Horizon** | **Where to find the parameter in East Horizon** | **Name of the variable in the R script** |
|---|---|---|
| Probability of Dropout: Control | Response Card, Dropout Rate tab | *DropParamControl* |
| Probability of Dropout: Treatment | Response Card, Dropout Rate tab | *DropParamtrt* |

The figure below illustrates where this example fits within the R integration points of Cytel products, accompanied by a flowchart outlining the general steps performed by the R code.