

# Sample Size for Premises Studies Supporting Document

## Executive Summary

This document is directly related to the Premises Guideline, Charge Question #11.

Briefly, the revision of the Premises Guideline provides an opportunity to assess sample sizes from a statistical standpoint. Historically, the Agency has often received basic laboratory studies which utilize 5 replicates of 10 individuals per replicate, or fewer. This sample size has become somewhat of an industry standard that is logistically convenient. However, no statistical modelling had been conducted to evaluate the statistical power of this experimental design to detect a treatment-related effect.

Here, we provide statistical simulations which illustrate the potential power of laboratory studies that utilize 5 replicates of 10 individuals, in addition to other numbers of replicates and individuals. The appropriate number of replicates and individuals might vary according to test species, background levels of mortality and variability, and other factors. For example, tests on some arthropod species (e.g., spiders, scorpions, and centipedes) may only be successful with one individual per test chamber. Therefore, simulations were also conducted to evaluate statistical power when using only one individual per replicate.

The standard, 5 replicates of 10 individuals per replicate provides power of 0.8 with 15% or 20% precision. However, with a precision of 10%, the same replication only provides a power of 0.6. The simulations demonstrate which sample sizes and configurations are expected to attain the standard, generally accepted statistical power of 0.80. They apply to, but are not limited to, laboratory studies for direct application testing of pesticide products, studies for forced exposure (no-choice) indoor and outdoor residual applications, and laboratory studies for testing bait products. Assuming control mortality of 5% and treatment adjusted survival of 5% and reasonable assumed values for replicate variability (as measured by RepVar), then a study with 5 replicates of 15 individuals per replicate, or 7 replicates of 10 individuals per replicate, or 35 replicates with 1 individual per replicate are likely to achieve a statistical power at least 0.80 for the observed control mortality of at most 0.1 and the observed treatment-adjusted survival rate of at most 0.1 at a precision of 0.10.

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### Study design and Outcomes

- Study design:
  - o 1 control group and at least 1 treatment group
  - o **Nrep** replicates/group, **Nprep** insects/replicate
- Outcomes:
  - o Counts of dead/survived insects per replicate
  - o Counts of flushed/remaining insects per replicate
  - o Others

### Data characteristics

- Assume that:
  - o There are two groups: control group and treatment group
  - o The true overall survival rate of all insects in the  $i^{th}$  group is  $\pi_i$  (the survival rate of control group is  $\pi_0$ , denoted as **CP** in SAS code, and the survival rate of treatment group is  $\pi_1$ , denoted as **TP** in SAS code).
  - o The true adjusted survival rate of treatment group is  $\pi_t$  where  $(\pi_t = \pi_1 \times \pi_0)$
- Without replicate effect, the number of surviving insects per replicate in the  $i^{th}$  group follows a binomial distribution  $B(Nprep, \pi_i)$ .
- Due to the differences between replicates within a group (due to different arena, time, temperature, etc. and additionally, amount of product applied if the group is treatment group), the survival rates are different among replicates. Let the survival rate of replicate  $j$  in group  $i$  be  $\pi_{ij}$ . The number of surviving insects of replicate  $j$  in group  $i$  would follow the binomial distribution  $B(Nprep, \pi_{ij})$ . However, the overall survival rate of all replicates in group  $i$  is  $\pi_i$ .

**EPA accepts and determines a product is acceptable if the data of a study meet all 3 of the following requirements:**

- **Observed survival rate of control group is  $\geq 90\%$**
- **Observed adjusted survival rate of treatment group is  $\leq$  the allowed maximum adjusted survival rate **ReqATP= 10%****
- **The upper limit of 95% CI of observed adjusted survival rate of treatment group  $\leq$  the allowed maximum adjusted survival rate **ReqATP + precision = 10% + precision.****

### Data Simulation

A SAS program was developed and used to conduct the simulation (i.e. Monte Carlo) to determine a study's sample size and power that the data of a product will need to meet the EPA requirements.

#### Parameters in simulation

- Survival rate of control (**CP**)
  - o The true survival rate of control population is set to be 0.95, 0.975, or 1
  - o The power of a study design is expected to increase as the true survival rate of control group increases from 0.95 to 1.
- Allowed maximum adjusted survival rate in the treated group (**ReqATP**)
  - o If **ReqATP** = the true adjusted survival rate of treatment group (**ATP**):
    - half of the studies are expected to have the observed adjusted survival rates  $>$  **ReqATP**

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- half of the studies are expected to have the observed adjusted survival rates < **ReqATP**
    - As the value of **ReqATP** decreases, the proportion of studies with observed adjusted survival rate < the **ReqATP** decreases.
    - As the value of **ReqATP** increases, the proportion of studies with observed adjusted survival rate < **ReqATP** increases.
    - EPA requires the observed adjusted survival rate of treatment group to be at most = **ReqATP** = 10%.
  - True adjusted survival rate of treatment (**ATP**)
    - If the true survival rate of treatment is **ATP** = 10%:
      - half of the studies are expected to have the observed adjusted survival rates ≤ 10%
      - half of the studies are expected to have the observed adjusted survival rates > 10%.
    - Given the EPA requirements that the observed adjusted survival rates of treatment must be ≤ 10% and the precision ≤ 10%, the power of study design is always ≤ 50% if the **ATP** = **ReqATP**, regardless any sample size values (even very large number of replicates and very large number of insects/replicate).
    - As the true survival rate of treatment decreases and is < 10%, the proportion of the studies with observed adjusted survival rates ≤ 10% will increase. Therefore, the **ATP** must be smaller than 10% when EPA requires the observed adjusted survival rate no more than 10% in order a study design to have sufficient power.
    - The **ATP** are set as **ATP** = **0.025**, **0.05**, and **0.075** in the simulation. As indicated above, the power of the study design would decrease as the true adjusted survival rate increases from 0.025 to 0.075.
  - Variability between replicates (**RepVar**)
    - This parameter determined the variation between replicates (i.e. variation between true survival rates of the replicates due to different arena, time, temperature, etc. and additionally, amount of product applied if the replicate is in the treatment group)
    - The variation of true survival rates of replicates in treatment group may be greater than control group due to the additional variation due to different amount of product applied between replicates. However, for simplicity, the degree of variation between replicates is assumed to be the same between control group and treatment group.
    - Since there is no currently available information about the best value for the premise studies, the effects of different values of **RepVar** (due to different time, temperature, materials, etc.) on the true survival rates of replicates can be examined in Table 10. Given a belief of how much the difference of time, temperature, materials between replicates, etc., can vary the true survival rate, a reasonable value of **RepVar** can be selected. For example, based on the distribution of 1000 randomly simulated replicates when the true survival rate  $\pi = 0.5$  in the below table (extracted from Table 10), a value of **RepVar** ≤ 1 can reasonably represent or express the variation in true survival rate due to the of differences time, temperatures, material, etc. between the replicates.

<i>RepVar</i>	$\pi$	Distribution of random $\pi_i$ of 1000 replicates per RepVar				
		Minimum	25th Pctl	50th Pctl	75th Pctl	Maximum
0	0.5	0.500	0.500	0.500	0.500	0.500
0.5	0.5	0.381	0.453	0.500	0.556	0.784

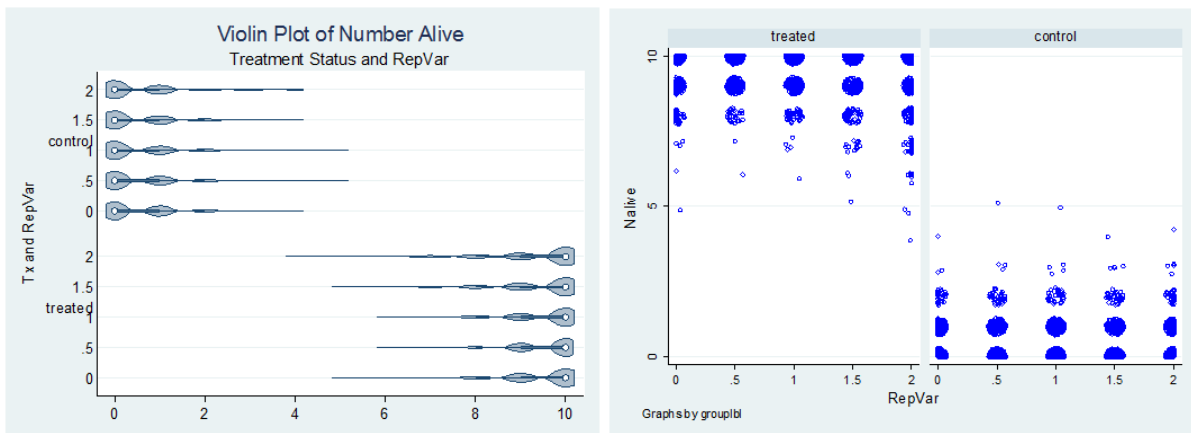
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RepVar	$\pi$	Distribution of random $\pi_i$ of 1000 replicates per RepVar				
		Minimum	25th Pctl	50th Pctl	75th Pctl	Maximum
1.0	0.5	0.275	0.407	0.501	0.611	0.930
1.5	0.5	0.190	0.363	0.501	0.664	0.980
2.0	0.5	0.126	0.321	0.501	0.712	0.994

- The determination of reasonable value for **RepVar** was also evaluated by observing the data distribution of 100 simulated datasets for each of **RepVar** = 0, 0.5, 1, 1.5, and 2; each dataset included 1 control group and 1 treatment group, 5 replicates/group, and 10 insects/replicate. The true survival rates in control group and treatment group are 95% and 4.75% (i.e. adjusted survival rate = 5%), respectively. Below is the summary table of all replicates for each value of **RepVar**.

Group	Nalive	Frequencies of replicates				
		RepVar = 0	RepVar = 0.5	RepVar = 1	RepVar = 1.5	RepVar = 2
0	4					1
0	5	1			1	2
0	6	1	1	1	2	8
0	7	3	1	4	14	27
0	8	41	27	44	51	56
0	9	148	149	127	125	111
0	10	306	322	324	307	295
1	0	295	311	314	313	310
1	1	171	149	145	146	150
1	2	31	36	36	36	35
1	3	2	3	4	4	4
1	4	1			1	1
1	5		1	1		

The below Figures (violin on the left and scatter plot on the right) visually show the frequencies of replicates by group and **RepVar** value.



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The effects of **RepVar** = 1.5 and 2 are shown in the frequencies of replicates with number of surviving insects  $\leq 7$  in the control group in the Table and Figures above.

- **RepVar** = 0, 0.5, 1, 1.5, and 2 were used in the simulations.
- Number of replicates/group (**Nrep**)
  - The **Nrep** is set to be 3, 4, 5, ..., 10 in the simulations. **Nrep** is also set to be 20, 21, ..., 40 only for simulations with **Nprep** = 1.
  - However, it should be noted that the power of study design may be incorrectly inflated when the **Nrep** is too small. This happens because when the number of replicates are too small, the studies will underestimate the variation of the true distribution. For example, if the study design has only 1 replicate per group, the variability in the data is purely due to the variation between insects and the true variability between replicates does not exist in the data, and the variation in the data is underestimating the variation of the true distribution. This leads to the power of the study design is incorrectly inflated due to under-estimated variation of the true distribution. If the number of replicates  $> 1$ , the variability in the data is estimated by accounting the variation between insects and variation between replicates.
  - As the **Nrep** increases, the power of the study design increases.
- Number of insects/replicate **Nprep**
  - The **Nprep** is set to be 5, 10, and 15 in the simulation. However, the **Nprep** can be changed to any value.
  - For simulations with **Nrep** = 20, 21, ..., 40, **Nprep** is set to be 1.
  - As the **Nprep** increases, the power of the study design increases.
- Precision
  - Precision of an **estimate of adjusted survival rate** is the **upper limit of 95% CI** of the observed adjusted survival rate - the **ReqATP**.
  - The required precision levels are set 10%, 15%, 20%, and 25% in the simulations.

### Data generating mechanism

Below is the mechanism of data generation. The mechanism of data generation is validated by a separate simulation showed in the Appendix 1.

- Control group with a true survival rate =  $\pi_0$
- Treatment group with the true survival rate  $\pi_1 = \pi_i \times \pi_0$ , where  $\pi_i$  is the adjusted survival rate of the treatment.
- Calculate the logit of overall survival rate  $\pi_i$  as  $QT_i = \log(\pi_i/(1 - \pi_i))$ ,  $i = 0$  or  $1$ .
- To create replicate effect of a replicate  $j$  of group  $i$ , the true logit of the replicate is set as  $QT_{subij} = QT_i + v_{ij}$ , where:
  - $v_{ij} = 0$  if  $\pi_i = 0$  or  $1$  or the given degree of variation between replicate  $RepVar = 0$
  - $v_{ij} = w - RepVar$  if  $0 < \pi_i < 1$  and the given degree of variation between replicate  $0 < RepVar$ , where  $w$  is randomly generated from a 2-parameter Weibull distribution having cumulative distribution function

$$CPF = 1 - e^{-\left(\frac{w}{\lambda}\right)^k}$$

where  $w \in (0, +\infty)$ , scale parameter  $\lambda = 1/\pi_i$ , and shape parameter  $k =$

$$e^{\frac{\ln\left(-\frac{RepVar^\lambda}{\ln(0.5)}\right)}{\lambda}}.$$

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This will set the Weibull distribution to have a median = *RepVar*; therefore, the expected median of all  $v_{ij}$ 's of group  $i$  is 0.

- Calculate the true survival rate of replicate  $j$  in group  $i$  as:

$$\pi_{ij} = \frac{e^{Q_{subij}}}{1+e^{Q_{subij}}}$$

- The number of surviving insects for replicate  $j$  of group  $i$  is randomly generated from a binomial distribution of  $N_{prep}$  trials and success rate =  $\pi_{ij}$ ,  $B(N_{prep}, \pi_{ij})$ .

### Simulated Datasets

For each of different combination of parameters' input values:  $\pi_0$  (**CP** = true survival rate of control group =  $\pi_0$ , and  $\pi_0 \geq 90\%$ ), adjusted survival rate of treatment group  $\pi_t$  (**ATP**), degree of variation between replicates (**RepVar**), number replicates per group (**Nrep**), and number of insects per replicate (**Nprep**), 1000 iterations (datasets), each include 1 control group and 1 treatment group, were randomly created.

### Determination of PASS or FAIL for each simulated dataset

A "PASS" is given to each dataset if all three following EPA requirements are met:

- 1) observed survival rate of control group  $\geq 90\%$  and
- 2) the **observed adjusted survival rate** of the treatment group  $\leq ReqATP = 10\%$  and
- 3) the **upper limit of 95% CI** of the observed survival rate of the treatment group  $\leq ReqATP + precision = 10\% + precision$

Below are 9 different potential outcomes of a dataset. Depending on outcome of the dataset, the appropriate analysis would be done.

- **Outcome 1:** No insects in control group survived and no insects in treatment group survived.
  - o FAIL, the observed survival rate in the control  $< 90\%$
- **Outcome 2:** No insects in control group survived and some insects in treatment group survived.
  - o FAIL, the observed survival rate in the control  $< 90\%$
- **Outcome 3:** No insects in control group survived and all insects in treatment group survived.
  - o FAIL, the observed survival rate in the control  $< 90\%$
- **Outcome 4:** Some insects in control group survived and no insects in treatment group survived.

A generalized linear model is used to estimate the survival rate of control group.

  - o PASS if the observed survival rate in the control  $\geq 90\%$
  - o FAIL if the observed survival rate in the control  $< 90\%$
- **Outcome 5:** All insects in control group survived and no insects in treatment group survived.
  - o PASS
- **Outcome 6:** Some insects in control group survived and some insects in treatment group survived. A generalized linear model for binomial distribution with log-link function is used to

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analyze the dataset and estimate the observed adjusted survival rate of treatment group and its 95% CI for each dataset.

- PASS if:
  - Observed survival rate of control group  $\geq 90\%$  and
  - the observed adjusted survival rate of the treatment group  $\leq$  allowed maximum adjusted survival rate  $ReqATP = 10\%$  and
  - the **upper limit of 95% CI** of the observed adjusted survival rate of the treatment group  $\leq ReqATP + precision = 10\% + precision$
- FAIL if:
  - Observed survival rate of control group  $< 90\%$ , or
  - the observed adjusted survival rate of the treatment group  $> ReqATP = 10\%$ , or
  - the **upper limit of 95% CI** of the observed adjusted survival rate of the treatment group  $> ReqATP + precision = 10\% + precision$
- **Outcome 7: All insects in control group survived and some insects in treatment group survived.**  
A generalized linear model is used to estimate the survival rate of the treatment group.
  - PASS if:
    - the observed survival rate of the treatment group  $\leq ReqATP = 10\%$  and
    - the **upper limit of 95% CI** of the observed survival rate of the treatment group  $\leq ReqATP + precision = 10\% + precision$
  - FAIL if:
    - the observed survival rate of the treatment group  $> ReqATP = 10\%$ , or
    - the **upper limit of 95% CI** of the observed survival rate of the treatment group  $> ReqATP + precision = 10\% + precision$
- **Outcome 8: Some insects in control group survived and all insects in treatment group survived.**
  - FAIL, observed survival rate of treatment group  $> ReqATP = 10\%$
- **Outcome 9: All insects in control group survived and all insects in treatment group survived.**
  - FAIL, observed survival rate of treatment group  $> ReqATP = 10\%$

### Power of study design

The proportion of PASS datasets will be the power of the study design given the EPA requirements.

### SAS code



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2.sas

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### Results of simulation

CP: true survival rate of control group

TP: survival rate of treatment group

ATP: adjusted survival rate of treatment group

ReqATP: allowed maximum adjusted survival rate of treatment group

ReqCP: allowed minimum observed survival rate in the control group

NPRep: number of insects/replicate

Nrepep: number of replicates/group

RepVar = 0, 0.5, and 1 (degree of variation between replicates, i.e. random effects of replicates)

Tables 1, 2, ..., 5 are the results of simulation when the input values are set as **CP = 0.95, ATP = 0.05, ReqATP=0.1, ReqCP=0.9** and **RepVar = 0, 0.5, 1, 1.5, and 2**. The results show that the power of the study design decrease as **RepVar** increase from 0 to 2. The power of study design slightly decreases when **RepVar** increases from 0 to 1; however, the power substantially decreases as **RepVar** increases from 1 to 2. Note that **RepVar** expresses the degree of variation in the survival rates due to the replicates (different time, different materials, different temperatures, etc.).

Table 1: Power and Sample Size given CP = 0.95, ATP = 0.05, ReqATP=0.1, ReqCP=0.9, and RepVar = 0									
CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
0.95	0.05	0.1	3	5	0.384	0.384	0.384	0.384	0.178
				10	0.191	0.406	0.592	0.649	0.087
				15	0.456	0.650	0.757	0.830	0.073
0.95	0.05	0.1	4	5	0.271	0.271	0.409	0.561	0.149
				10	0.483	0.609	0.788	0.827	0.049
				15	0.678	0.846	0.904	0.912	0.028
0.95	0.05	0.1	5	5	0.233	0.508	0.693	0.734	0.117
				10	0.614	0.795	0.852	0.864	0.054
				15	0.843	0.919	0.928	0.928	0.035
0.95	0.05	0.1	6	5	0.381	0.611	0.721	0.750	0.104
				10	0.766	0.871	0.890	0.890	0.035
				15	0.926	0.947	0.947	0.947	0.015
0.95	0.05	0.1	7	5	0.534	0.704	0.810	0.827	0.104
				10	0.852	0.921	0.926	0.926	0.020
				15	0.953	0.963	0.963	0.963	0.018
0.95	0.05	0.1	8	5	0.672	0.805	0.838	0.839	0.071
				10	0.921	0.942	0.944	0.944	0.027
				15	0.977	0.977	0.977	0.977	0.011
0.95	0.05	0.1	9	5	0.727	0.847	0.874	0.875	0.070
				10	0.943	0.962	0.962	0.962	0.014
				15	0.980	0.980	0.980	0.980	0.008
0.95	0.05	0.1	10	5	0.780	0.881	0.887	0.887	0.044



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Table 1: Power and Sample Size given CP = 0.95, ATP = 0.05, ReqATP=0.1, ReqCP=0.9, and RepVar = 0									
CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
				10	0.965	0.970	0.970	0.970	0.012
				15	0.991	0.991	0.991	0.991	0.002
0.95	0.05	0.1	20	1	0.568	0.612	0.612	0.612	0.178
			21	1	0.620	0.690	0.758	0.758	0.086
			22	1	0.671	0.802	0.802	0.802	0.090
			23	1	0.636	0.781	0.822	0.822	0.103
			24	1	0.626	0.767	0.803	0.803	0.118
			25	1	0.605	0.777	0.777	0.777	0.134
			26	1	0.710	0.765	0.765	0.765	0.126
			27	1	0.689	0.749	0.749	0.749	0.147
			28	1	0.660	0.735	0.735	0.735	0.150
			29	1	0.714	0.714	0.714	0.714	0.174
			30	1	0.717	0.738	0.738	0.738	0.132
			31	1	0.795	0.813	0.813	0.813	0.056
			32	1	0.772	0.833	0.833	0.833	0.064
			33	1	0.782	0.848	0.848	0.848	0.080
			34	1	0.780	0.840	0.840	0.840	0.087
			35	1	0.816	0.838	0.838	0.838	0.089
			36	1	0.805	0.834	0.834	0.834	0.091
			37	1	0.790	0.812	0.812	0.812	0.117
38	1	0.793	0.793	0.793	0.793	0.132			
39	1	0.796	0.796	0.796	0.796	0.126			
40	1	0.815	0.815	0.815	0.815	0.089			

Table 2: Power and Sample Size given CP = 0.95, ATP = 0.05, ReqATP=0.1, ReqCP=0.9, and RepVar = 0.5									
CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
0.95	0.05	0.1	3	5	0.397	0.397	0.397	0.397	0.143
				10	0.200	0.411	0.590	0.633	0.087
				15	0.444	0.613	0.748	0.807	0.062
0.95	0.05	0.1	4	5	0.285	0.285	0.424	0.571	0.173
				10	0.493	0.604	0.770	0.799	0.070
				15	0.640	0.824	0.893	0.905	0.039

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Table 2: Power and Sample Size given CP = 0.95, ATP = 0.05, ReqATP=0.1, ReqCP=0.9, and RepVar = 0.5									
CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
0.95	0.05	0.1	5	5	0.255	0.509	0.685	0.723	0.129
				10	0.612	0.789	0.850	0.857	0.057
				15	0.828	0.919	0.933	0.934	0.035
0.95	0.05	0.1	6	5	0.388	0.607	0.718	0.751	0.097
				10	0.752	0.881	0.901	0.904	0.034
				15	0.917	0.953	0.954	0.954	0.020
0.95	0.05	0.1	7	5	0.545	0.714	0.824	0.838	0.076
				10	0.842	0.911	0.912	0.912	0.028
				15	0.955	0.960	0.960	0.960	0.015
0.95	0.05	0.1	8	5	0.659	0.798	0.821	0.823	0.060
				10	0.904	0.940	0.940	0.940	0.020
				15	0.974	0.974	0.974	0.974	0.009
0.95	0.05	0.1	9	5	0.707	0.848	0.882	0.883	0.062
				10	0.940	0.959	0.959	0.959	0.014
				15	0.981	0.982	0.982	0.982	0.007
0.95	0.05	0.1	10	5	0.754	0.863	0.869	0.870	0.045
				10	0.960	0.965	0.965	0.965	0.016
				15	0.986	0.986	0.986	0.986	0.007
0.95	0.05	0.1	20	1	0.564	0.626	0.626	0.626	0.152
			21	1	0.623	0.690	0.753	0.753	0.069
			22	1	0.645	0.796	0.796	0.796	0.086
			23	1	0.641	0.768	0.809	0.809	0.085
			24	1	0.605	0.747	0.807	0.807	0.114
			25	1	0.590	0.798	0.798	0.798	0.123
			26	1	0.705	0.762	0.762	0.762	0.135
			27	1	0.686	0.744	0.744	0.744	0.143
			28	1	0.663	0.725	0.725	0.725	0.140
			29	1	0.720	0.720	0.720	0.720	0.155
			30	1	0.713	0.737	0.737	0.737	0.130
			31	1	0.776	0.799	0.799	0.799	0.059
			32	1	0.746	0.814	0.814	0.814	0.069
			33	1	0.770	0.843	0.843	0.843	0.068
			34	1	0.787	0.855	0.855	0.855	0.086
			35	1	0.829	0.848	0.848	0.848	0.082
			36	1	0.810	0.835	0.835	0.835	0.092
37	1	0.781	0.811	0.811	0.811	0.101			
38	1	0.811	0.811	0.811	0.811	0.094			
39	1	0.789	0.789	0.789	0.789	0.116			

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Table 2: Power and Sample Size given CP = 0.95, ATP = 0.05, ReqATP=0.1, ReqCP=0.9, and RepVar = 0.5									
CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
			40	1	0.808	0.808	0.808	0.808	0.084

Table 3: Power and Sample Size given CP = 0.95, ATP = 0.05, ReqATP=0.1, ReqCP=0.9, and RepVar = 1										
CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9	
0.95	0.05	0.1	3	5	0.379	0.379	0.379	0.379	0.176	
				10	0.184	0.363	0.536	0.576	0.127	
				15	0.395	0.559	0.673	0.753	0.105	
0.95	0.05	0.1	4	5	0.273	0.273	0.395	0.544	0.202	
				10	0.439	0.557	0.721	0.770	0.105	
				15	0.574	0.746	0.836	0.858	0.085	
0.95	0.05	0.1	5	5	0.243	0.475	0.656	0.693	0.166	
				10	0.556	0.735	0.811	0.825	0.087	
				15	0.755	0.863	0.887	0.892	0.070	
0.95	0.05	0.1	6	5	0.342	0.566	0.681	0.714	0.134	
				10	0.699	0.845	0.877	0.878	0.063	
				15	0.868	0.923	0.927	0.927	0.049	
0.95	0.05	0.1	7	5	0.494	0.671	0.780	0.797	0.121	
				10	0.798	0.885	0.893	0.893	0.051	
				15	0.917	0.931	0.931	0.931	0.044	
0.95	0.05	0.1	8	5	0.617	0.750	0.795	0.797	0.094	
				10	0.866	0.916	0.916	0.916	0.048	
				15	0.949	0.952	0.952	0.952	0.031	
0.95	0.05	0.1	9	5	0.669	0.810	0.845	0.846	0.102	
				10	0.909	0.934	0.934	0.934	0.038	
				15	0.955	0.957	0.957	0.957	0.031	
0.95	0.05	0.1	10	5	0.719	0.831	0.839	0.840	0.074	
				10	0.927	0.941	0.941	0.941	0.043	
				15	0.972	0.973	0.973	0.973	0.019	
0.95	0.05	0.1		20	1	0.535	0.604	0.604	0.604	0.182
				21	1	0.597	0.680	0.738	0.738	0.087
				22	1	0.635	0.775	0.775	0.775	0.108
				23	1	0.624	0.732	0.786	0.786	0.116

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<b>Table 3: Power and Sample Size</b> given CP = 0.95, ATP = 0.05, ReqATP=0.1, ReqCP=0.9, and RepVar = 1									
CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
			24	1	0.585	0.716	0.774	0.774	0.152
			25	1	0.564	0.758	0.758	0.758	0.174
			26	1	0.677	0.737	0.737	0.737	0.170
			27	1	0.658	0.717	0.717	0.717	0.177
			28	1	0.624	0.686	0.686	0.686	0.188
			29	1	0.693	0.693	0.693	0.693	0.193
			30	1	0.697	0.723	0.723	0.723	0.150
			31	1	0.763	0.777	0.777	0.777	0.079
			32	1	0.731	0.788	0.788	0.788	0.101
			33	1	0.732	0.800	0.800	0.800	0.107
			34	1	0.762	0.835	0.835	0.835	0.106
			35	1	0.796	0.816	0.816	0.816	0.117
			36	1	0.768	0.794	0.794	0.794	0.135
			37	1	0.749	0.781	0.781	0.781	0.133
			38	1	0.770	0.770	0.770	0.770	0.140
			39	1	0.750	0.750	0.750	0.750	0.155
			40	1	0.782	0.782	0.782	0.782	0.114

<b>Table 4: Power and Sample Size</b> given CP = 0.95, ATP = 0.05, ReqATP=0.1, ReqCP=0.9, and RepVar = 1.5									
CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
0.95	0.05	0.1	3	5	0.359	0.359	0.359	0.359	0.226
				10	0.172	0.334	0.475	0.528	0.187
				15	0.339	0.460	0.573	0.653	0.182
0.95	0.05	0.1	4	5	0.259	0.259	0.363	0.496	0.250
				10	0.367	0.486	0.635	0.689	0.176
				15	0.454	0.631	0.720	0.761	0.171
0.95	0.05	0.1	5	5	0.226	0.428	0.599	0.631	0.228
				10	0.471	0.631	0.711	0.729	0.193
				15	0.617	0.751	0.786	0.790	0.167
0.95	0.05	0.1	6	5	0.290	0.511	0.615	0.648	0.216
				10	0.607	0.761	0.808	0.813	0.134
				15	0.746	0.824	0.831	0.831	0.143
0.95	0.05	0.1	7	5	0.447	0.598	0.711	0.737	0.188
				10	0.698	0.804	0.822	0.822	0.128

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<b>Table 4: Power and Sample Size</b> given CP = 0.95, ATP = 0.05, ReqATP=0.1, ReqCP=0.9, and RepVar = 1.5									
CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
				15	0.811	0.844	0.845	0.845	0.133
0.95	0.05	0.1	8	5	0.547	0.676	0.750	0.752	0.143
				10	0.776	0.850	0.854	0.854	0.110
				15	0.860	0.876	0.876	0.876	0.108
0.95	0.05	0.1	9	5	0.600	0.729	0.777	0.781	0.172
				10	0.834	0.871	0.871	0.871	0.103
				15	0.881	0.885	0.885	0.885	0.105
0.95	0.05	0.1	10	5	0.640	0.766	0.779	0.779	0.137
				10	0.841	0.866	0.866	0.866	0.118
				15	0.898	0.901	0.901	0.901	0.092
0.95	0.05	0.1	20	1	0.473	0.543	0.543	0.543	0.251
			21	1	0.556	0.650	0.697	0.697	0.135
			22	1	0.589	0.706	0.706	0.706	0.176
			23	1	0.581	0.676	0.733	0.733	0.182
			24	1	0.545	0.658	0.725	0.725	0.209
			25	1	0.518	0.693	0.693	0.693	0.248
			26	1	0.628	0.679	0.679	0.679	0.238
			27	1	0.584	0.645	0.645	0.645	0.262
			28	1	0.557	0.628	0.628	0.628	0.260
			29	1	0.619	0.619	0.619	0.619	0.279
			30	1	0.634	0.662	0.662	0.662	0.226
			31	1	0.712	0.725	0.725	0.725	0.140
			32	1	0.679	0.730	0.730	0.730	0.161
			33	1	0.667	0.730	0.730	0.730	0.182
			34	1	0.695	0.766	0.766	0.766	0.180
			35	1	0.715	0.747	0.747	0.747	0.193
			36	1	0.698	0.731	0.731	0.731	0.206
37	1	0.673	0.702	0.702	0.702	0.222			
38	1	0.689	0.689	0.689	0.689	0.232			
39	1	0.669	0.669	0.669	0.669	0.246			
40	1	0.736	0.736	0.736	0.736	0.173			

<b>Table 5: Power and Sample Size</b> given CP = 0.95, ATP = 0.05, ReqATP=0.1, ReqCP=0.9, and RepVar = 2									
CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
0.95	0.05	0.1	3	5	0.311	0.311	0.311	0.311	0.316

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Table 5: Power and Sample Size given CP = 0.95, ATP = 0.05, ReqATP=0.1, ReqCP=0.9, and RepVar = 2											
CP	AT P	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9		
				10	0.143	0.270	0.386	0.436	0.300		
				15	0.273	0.385	0.465	0.526	0.311		
0.95	0.05	0.1	4	5	0.226	0.226	0.306	0.416	0.330		
				10	0.283	0.372	0.512	0.575	0.294		
				15	0.339	0.486	0.590	0.639	0.289		
0.95	0.05	0.1	5	5	0.198	0.362	0.504	0.536	0.320		
				10	0.355	0.501	0.598	0.619	0.308		
				15	0.451	0.591	0.643	0.651	0.313		
0.95	0.05	0.1	6	5	0.227	0.405	0.513	0.548	0.329		
				10	0.456	0.607	0.676	0.689	0.262		
				15	0.565	0.679	0.699	0.703	0.277		
0.95	0.05	0.1	7	5	0.349	0.497	0.593	0.633	0.301		
				10	0.558	0.672	0.696	0.697	0.261		
				15	0.626	0.696	0.699	0.699	0.283		
0.95	0.05	0.1	8	5	0.444	0.566	0.642	0.648	0.264		
				10	0.625	0.708	0.716	0.716	0.247		
				15	0.712	0.739	0.740	0.740	0.244		
0.95	0.05	0.1	9	5	0.501	0.609	0.664	0.669	0.293		
				10	0.675	0.739	0.740	0.740	0.234		
				15	0.719	0.730	0.730	0.730	0.260		
0.95	0.05	0.1	10	5	0.534	0.660	0.682	0.684	0.246		
				10	0.688	0.722	0.723	0.723	0.259		
				15	0.746	0.754	0.754	0.754	0.241		
0.95	0.05	0.1		20	1	0.400	0.468	0.468	0.468	0.342	
				21	1	0.484	0.583	0.613	0.613	0.613	0.216
				22	1	0.534	0.627	0.627	0.627	0.627	0.255
				23	1	0.519	0.592	0.648	0.648	0.648	0.273
				24	1	0.486	0.571	0.642	0.642	0.642	0.304
				25	1	0.445	0.599	0.599	0.599	0.599	0.349
				26	1	0.520	0.569	0.569	0.569	0.569	0.361
				27	1	0.475	0.544	0.544	0.544	0.544	0.383
				28	1	0.447	0.525	0.525	0.525	0.525	0.384
				29	1	0.513	0.513	0.513	0.513	0.513	0.400
				30	1	0.529	0.567	0.567	0.567	0.567	0.340
				31	1	0.627	0.635	0.635	0.635	0.635	0.236
				32	1	0.610	0.644	0.644	0.644	0.644	0.254
				33	1	0.589	0.635	0.635	0.635	0.635	0.289
	34	1	0.587	0.654	0.654	0.654	0.654	0.302			
				35	1	0.609	0.645	0.645	0.645	0.307	

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**Table 5: Power and Sample Size**  
 given CP = 0.95, ATP = 0.05, ReqATP=0.1, ReqCP=0.9, and RepVar = 2

CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
			36	1	0.579	0.619	0.619	0.619	0.333
			37	1	0.561	0.599	0.599	0.599	0.337
			38	1	0.580	0.580	0.580	0.580	0.359
			39	1	0.556	0.556	0.556	0.556	0.383
			40	1	0.620	0.620	0.620	0.620	0.309

**Table 6: Power and Sample Size**  
 given CP = 0.975, ATP = 0.05, ReqATP=0.1, ReqCP=0.9, and RepVar = 1

CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
0.975	0.05	0.1	3	5	0.439	0.439	0.439	0.439	0.053
				10	0.218	0.472	0.682	0.698	0.024
				15	0.526	0.677	0.824	0.866	0.011
0.975	0.05	0.1	4	5	0.349	0.349	0.566	0.694	0.057
				10	0.585	0.658	0.835	0.852	0.010
				15	0.718	0.863	0.911	0.922	0.006
0.975	0.05	0.1	5	5	0.281	0.603	0.789	0.811	0.032
				10	0.638	0.844	0.895	0.902	0.009
				15	0.873	0.953	0.968	0.969	0.001
0.975	0.05	0.1	6	5	0.479	0.717	0.776	0.801	0.030
				10	0.811	0.921	0.929	0.931	0.003
				15	0.936	0.965	0.967	0.967	0.001
0.975	0.05	0.1	7	5	0.649	0.798	0.881	0.887	0.017
				10	0.884	0.933	0.935	0.935	0.002
				15	0.969	0.976	0.976	0.976	0.001
0.975	0.05	0.1	8	5	0.743	0.854	0.863	0.865	0.013
				10	0.936	0.956	0.956	0.956	0.001
				15	0.981	0.981	0.981	0.981	0.000
0.975	0.05	0.1	9	5	0.771	0.913	0.931	0.931	0.008
				10	0.957	0.963	0.963	0.963	0.001
				15	0.993	0.994	0.994	0.994	0.000
0.975	0.05	0.1	10	5	0.839	0.896	0.903	0.903	0.001
				10	0.978	0.980	0.980	0.980	0.000
				15	0.993	0.993	0.993	0.993	0.000
0.975	0.05	0.1	20	1	0.678	0.701	0.701	0.701	0.055

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Table 6: Power and Sample Size given CP = 0.975, ATP = 0.05, ReqATP=0.1, ReqCP=0.9, and RepVar = 1									
CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
			21	1	0.700	0.727	0.830	0.830	0.019
			22	1	0.683	0.868	0.868	0.868	0.028
			23	1	0.675	0.842	0.865	0.865	0.019
			24	1	0.650	0.851	0.878	0.878	0.031
			25	1	0.641	0.870	0.870	0.870	0.035
			26	1	0.814	0.838	0.838	0.838	0.044
			27	1	0.805	0.835	0.835	0.835	0.035
			28	1	0.770	0.808	0.808	0.808	0.042
			29	1	0.806	0.806	0.806	0.806	0.044
			30	1	0.814	0.823	0.823	0.823	0.026
			31	1	0.810	0.849	0.849	0.849	0.010
			32	1	0.791	0.898	0.898	0.898	0.009
			33	1	0.810	0.908	0.908	0.908	0.013
			34	1	0.883	0.918	0.918	0.918	0.014
			35	1	0.891	0.902	0.902	0.902	0.015
			36	1	0.881	0.889	0.889	0.889	0.028
			37	1	0.866	0.878	0.878	0.878	0.016
			38	1	0.880	0.880	0.880	0.880	0.020
			39	1	0.854	0.854	0.854	0.854	0.027
			40	1	0.858	0.858	0.858	0.858	0.020

Table 7: Power and Sample Size given CP = 1, ATP = 0.05, ReqATP=0.1, ReqCP=0.9, and RepVar = 1									
CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
1.00	0.05	0.1	3	5	0.443	0.443	0.443	0.443	0.000
				10	0.220	0.713	0.744	0.744	0.000
				15	0.619	0.749	0.870	0.902	0.000
1.00	0.05	0.1	4	5	0.326	0.326	0.736	0.736	0.000
				10	0.650	0.664	0.862	0.862	0.000
				15	0.794	0.850	0.908	0.912	0.000
1.00	0.05	0.1	5	5	0.267	0.631	0.845	0.845	0.000
				10	0.624	0.853	0.893	0.893	0.000
				15	0.891	0.947	0.962	0.963	0.000
1.00	0.05	0.1	6	5	0.538	0.784	0.784	0.823	0.000



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Table 7: Power and Sample Size given CP = 1, ATP = 0.05, ReqATP=0.1, ReqCP=0.9, and RepVar = 1									
CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
				10	0.851	0.921	0.923	0.923	0.000
				15	0.942	0.960	0.962	0.962	0.000
1.00	0.05	0.1	7	5	0.711	0.823	0.905	0.905	0.000
				10	0.895	0.940	0.942	0.942	0.000
				15	0.975	0.984	0.984	0.984	0.000
1.00	0.05	0.1	8	5	0.787	0.867	0.867	0.868	0.000
				10	0.923	0.951	0.951	0.951	0.000
				15	0.974	0.974	0.974	0.974	0.000
1.00	0.05	0.1	9	5	0.750	0.921	0.929	0.929	0.000
				10	0.946	0.953	0.953	0.953	0.000
				15	0.993	0.993	0.993	0.993	0.000
1.00	0.05	0.1	10	5	0.832	0.884	0.886	0.886	0.000
				10	0.971	0.977	0.977	0.977	0.000
				15	0.993	0.993	0.993	0.993	0.000
1.00	0.05	0.1	20	1	0.726	0.726	0.726	0.726	0.000
			21	1	0.710	0.710	0.902	0.902	0.000
			22	1	0.701	0.896	0.896	0.896	0.000
			23	1	0.676	0.890	0.890	0.890	0.000
			24	1	0.650	0.888	0.888	0.888	0.000
			25	1	0.627	0.871	0.871	0.871	0.000
			26	1	0.854	0.854	0.854	0.854	0.000
			27	1	0.839	0.839	0.839	0.839	0.000
			28	1	0.836	0.836	0.836	0.836	0.000
			29	1	0.824	0.824	0.824	0.824	0.000
			30	1	0.820	0.820	0.820	0.820	0.000
			31	1	0.811	0.927	0.927	0.927	0.000
			32	1	0.796	0.923	0.923	0.923	0.000
			33	1	0.772	0.923	0.923	0.923	0.000
			34	1	0.906	0.906	0.906	0.906	0.000
			35	1	0.912	0.912	0.912	0.912	0.000
			36	1	0.900	0.900	0.900	0.900	0.000
37	1	0.880	0.880	0.880	0.880	0.000			
38	1	0.889	0.889	0.889	0.889	0.000			
39	1	0.876	0.876	0.876	0.876	0.000			
40	1	0.855	0.855	0.855	0.855	0.000			

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Table 8: Power and Sample Size given CP = 0.95, ATP = 0.075, ReqATP=0.1, ReqCP=0.9, and RepVar = 1										
CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9	
0.95	0.075	0.1	3	5	0.249	0.249	0.249	0.249	0.176	
				10	0.102	0.254	0.389	0.427	0.107	
				15	0.251	0.383	0.494	0.587	0.105	
0.95	0.075	0.1	4	5	0.163	0.163	0.275	0.419	0.175	
				10	0.291	0.398	0.549	0.610	0.095	
				15	0.380	0.575	0.670	0.694	0.077	
0.95	0.075	0.1	5	5	0.138	0.324	0.508	0.548	0.166	
				10	0.318	0.539	0.630	0.650	0.084	
				15	0.536	0.686	0.720	0.724	0.070	
0.95	0.075	0.1	6	5	0.188	0.394	0.502	0.546	0.134	
				10	0.479	0.667	0.710	0.711	0.060	
				15	0.638	0.768	0.776	0.776	0.047	
0.95	0.075	0.1	7	5	0.320	0.497	0.649	0.674	0.121	
				10	0.580	0.726	0.743	0.743	0.050	
				15	0.733	0.786	0.786	0.786	0.044	
0.95	0.075	0.1	8	5	0.417	0.557	0.610	0.616	0.089	
				10	0.650	0.749	0.753	0.753	0.047	
				15	0.775	0.800	0.800	0.800	0.031	
0.95	0.075	0.1	9	5	0.452	0.634	0.698	0.699	0.102	
				10	0.712	0.787	0.788	0.788	0.038	
				15	0.814	0.822	0.822	0.822	0.031	
0.95	0.075	0.1	10	5	0.511	0.646	0.661	0.661	0.070	
				10	0.746	0.781	0.781	0.781	0.041	
				15	0.837	0.840	0.840	0.840	0.018	
0.95	0.075	0.1		20	1	0.404	0.457	0.457	0.457	0.155
				21	1	0.433	0.503	0.573	0.573	0.087
				22	1	0.459	0.638	0.638	0.638	0.108
				23	1	0.434	0.603	0.672	0.672	0.116
				24	1	0.408	0.579	0.653	0.653	0.152
				25	1	0.388	0.615	0.615	0.615	0.174
				26	1	0.532	0.601	0.601	0.601	0.170
				27	1	0.498	0.569	0.569	0.569	0.177
				28	1	0.491	0.550	0.550	0.550	0.188
				29	1	0.523	0.523	0.523	0.523	0.193
				30	1	0.544	0.565	0.565	0.565	0.135
				31	1	0.590	0.622	0.622	0.622	0.079
				32	1	0.556	0.652	0.652	0.652	0.101
33	1	0.573	0.654	0.654	0.654	0.107				

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**Table 8: Power and Sample Size**  
**given CP = 0.95, ATP = 0.075, ReqATP=0.1, ReqCP=0.9, and RepVar = 1**

CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
			34	1	0.609	0.696	0.696	0.696	0.106
			35	1	0.621	0.663	0.663	0.663	0.117
			36	1	0.601	0.628	0.628	0.628	0.135
			37	1	0.573	0.612	0.612	0.612	0.133
			38	1	0.604	0.604	0.604	0.604	0.140
			39	1	0.600	0.600	0.600	0.600	0.155
			40	1	0.606	0.606	0.606	0.606	0.101

**Table 9: Power and Sample Size**  
**given CP = 0.95, ATP = 0.025, ReqATP=0.1, ReqCP=0.9, and RepVar = 1**

CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
0.95	0.025	0.1	3	5	0.547	0.547	0.547	0.547	0.176
				10	0.379	0.544	0.697	0.739	0.147
				15	0.576	0.704	0.807	0.847	0.105
0.95	0.025	0.1	4	5	0.443	0.443	0.534	0.648	0.241
				10	0.648	0.724	0.835	0.853	0.125
				15	0.744	0.842	0.882	0.894	0.099
0.95	0.025	0.1	5	5	0.443	0.647	0.773	0.785	0.166
				10	0.758	0.848	0.885	0.890	0.102
				15	0.877	0.922	0.927	0.930	0.070
0.95	0.025	0.1	6	5	0.550	0.697	0.786	0.803	0.164
				10	0.864	0.918	0.925	0.926	0.073
				15	0.937	0.945	0.945	0.946	0.054
0.95	0.025	0.1	7	5	0.702	0.818	0.856	0.864	0.121
				10	0.928	0.946	0.946	0.946	0.053
				15	0.956	0.956	0.956	0.956	0.044
0.95	0.025	0.1	8	5	0.795	0.860	0.875	0.875	0.112
				10	0.939	0.947	0.947	0.947	0.053
				15	0.967	0.967	0.967	0.967	0.033
0.95	0.025	0.1	9	5	0.836	0.889	0.895	0.895	0.102
				10	0.958	0.961	0.961	0.961	0.039
				15	0.969	0.969	0.969	0.969	0.031
0.95	0.025	0.1	10	5	0.866	0.900	0.901	0.901	0.091
				10	0.956	0.956	0.956	0.956	0.044

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**Table 9: Power and Sample Size**  
**given CP = 0.95, ATP = 0.025, ReqATP=0.1, ReqCP=0.9, and RepVar = 1**

CP	ATP	Req ATP	N Rep	N per Rep	Power at Precision = 0.10	Power at Precision = 0.15	Power at Precision = 0.20	Power at Precision = 0.25	Observed Control survival proportion < 0.9
				15	0.980	0.980	0.980	0.980	0.020
0.95	0.025	0.1	20	1	0.648	0.703	0.703	0.703	0.230
			21	1	0.767	0.835	0.860	0.860	0.087
			22	1	0.812	0.862	0.862	0.862	0.108
			23	1	0.794	0.841	0.867	0.867	0.116
			24	1	0.767	0.817	0.841	0.841	0.152
			25	1	0.737	0.809	0.809	0.809	0.174
			26	1	0.784	0.810	0.810	0.810	0.170
			27	1	0.771	0.806	0.806	0.806	0.177
			28	1	0.755	0.787	0.787	0.787	0.188
			29	1	0.789	0.789	0.789	0.789	0.193
			30	1	0.788	0.800	0.800	0.800	0.178
			31	1	0.886	0.892	0.892	0.892	0.079
			32	1	0.867	0.881	0.881	0.881	0.101
			33	1	0.857	0.880	0.880	0.880	0.107
			34	1	0.870	0.888	0.888	0.888	0.106
			35	1	0.865	0.873	0.873	0.873	0.117
			36	1	0.844	0.855	0.855	0.855	0.135
			37	1	0.850	0.858	0.858	0.858	0.133
38	1	0.848	0.848	0.848	0.848	0.140			
39	1	0.834	0.834	0.834	0.834	0.155			
40	1	0.864	0.864	0.864	0.864	0.124			

### CONCLUSIONS:

Historically, the Agency has often received basic laboratory studies which utilize 5 replicates of 10 individuals per replicate, or fewer. This sample size has become somewhat of an industry standard that is logistically convenient. This sample size provides power of 0.8 with 15% or 20% precision. However, with a precision of 10%, the same replication only provides a power of 0.6. The purpose of the simulations performed here was to provide a more rigorous basis for estimating sample size, one that would meet certain precision objectives with respect to treatment-related effects with a given probability.

The simulations performed here demonstrate which sample sizes/configurations are expected to be able to attain the standard, generally-accepted statistical power of 0.80. They apply to, but are not limited to, laboratory studies for direct application testing of pesticide products, studies for forced exposure (no-choice) indoor and outdoor residual applications, and laboratory studies for testing bait products. Assuming control mortality of 5% and treatment adjusted survival of 5% and a RepVar value (indicative of replicate variability) of 0.5, then a study with 5 replicates of 15 individuals per replicate, or 7 replicates of 10 individuals per replicate, or 35 replicates with 1 individual per replicate is likely to achieve a

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statistical power of at least 0.80 for an observed control mortality of up to 0.1 and an observed treatment-adjusted survival rate of up to 0.1 at a precision of 0.10 (see Table 2). The estimated power associated with these sample sizes and configurations have been found to be generally robust/non-sensitive to the selected values of RepVar.

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### Appendix 1

#### Validation of data generating technique

The data generating technique is appropriate if both of the following conditions are met:

- Condition 1: The variation of survival rate  $\pi_j$ 's of the replicates increases as the input **RepVar** increases
- Condition 2: The observed survival rate of the simulated data is the best estimate of the  $\pi$  (the median of observed survival rates of a large number datasets is equal or close to the  $\pi$ )

To evaluate the first condition, a single dataset includes 1000 replicates was created for each of different combinations of  $\pi$  and the degree of variation **RepVar** between replicates. Table 10 below presents the resulting distributions of  $\pi_j$ 's of the replicate.

As shown in the table, when the **RepVar** = 0, all the true survival rates of the replicates are the same. For example, if the overall survival rate of the group = 0.5, the observed true survival rates of 1000 replicates are the same and equal 0.5.

When **RepVar** > 0, the true survival rates of the replicates are not the same. For example, if the **RepVar** = 1 and the overall survival rate of the group = 0.5, all the observed true survival rates of 1000 replicates are not the same. The median observed true survival rate is 0.501. One replicate has the lowest observed true survival rate = 0.275 and one replicate has the highest observed true survival rate = 0.930.

Table 10: Results of survival rates  $\pi_j$  of 1000 replicates given the true overall survival rate  $\pi$  and degree of variation **RepVar**

RepVar	$\pi$	Distribution of random $\pi_j$ of 1000 replicates				
		Minimum	25th Pctl	50th Pctl	75th Pctl	Maximum
0	0.05	0.050	0.050	0.050	0.050	0.050
	0.1	0.100	0.100	0.100	0.100	0.100
	0.2	0.200	0.200	0.200	0.200	0.200
	0.5	0.500	0.500	0.500	0.500	0.500
	0.8	0.800	0.800	0.800	0.800	0.800
	0.9	0.900	0.900	0.900	0.900	0.900
	0.95	0.950	0.950	0.950	0.950	0.950
0.5	0.05	0.044	0.049	0.050	0.051	0.053
	0.1	0.080	0.096	0.100	0.104	0.114
	0.2	0.147	0.187	0.200	0.213	0.259
	0.5	0.381	0.453	0.500	0.556	0.784
	0.8	0.709	0.754	0.800	0.858	0.991
	0.9	0.845	0.871	0.900	0.936	0.999
	0.95	0.920	0.934	0.950	0.970	1.000
1	0.05	0.038	0.048	0.050	0.052	0.057
	0.1	0.063	0.092	0.100	0.107	0.129
	0.2	0.106	0.174	0.200	0.227	0.327
	0.5	0.275	0.407	0.501	0.611	0.930
	0.8	0.596	0.702	0.801	0.901	1.000
	0.9	0.768	0.836	0.900	0.959	1.000

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RepVar	$\pi$	Distribution of random $\pi_j$ of 1000 replicates				
		Minimum	25th Pctl	50th Pctl	75th Pctl	Maximum
	0.95	0.875	0.913	0.950	0.982	1.000
1.5	0.05	0.033	0.047	0.050	0.053	0.061
	0.1	0.050	0.089	0.100	0.111	0.147
	0.2	0.076	0.162	0.200	0.241	0.404
	0.5	0.190	0.363	0.501	0.664	0.980
	0.8	0.473	0.644	0.801	0.932	1.000
	0.9	0.668	0.792	0.900	0.974	1.000
	0.95	0.809	0.887	0.950	0.989	1.000
2	0.05	0.029	0.046	0.050	0.054	0.065
	0.1	0.040	0.085	0.100	0.115	0.166
	0.2	0.053	0.151	0.200	0.257	0.486
	0.5	0.126	0.321	0.501	0.712	0.994
	0.8	0.353	0.581	0.801	0.954	1.000
	0.9	0.550	0.742	0.901	0.984	1.000
	0.95	0.721	0.853	0.950	0.993	1.000

Comments:

- As expected, there is no variation between  $\pi_j$ 's when the degree of variation between replicates **RepVar** = 0.
- The variation of  $\pi_j$ 's increases (i.e. wider range) as the input degree of variation between replicates **RepVar** increases.
- The median of survival rates ( $\pi_j$ 's) of 1000 simulated replicates is equal or very close to the true overall survival rate  $\pi$ .

To evaluate the second condition, 1000 datasets with a given number of replicates (5, 10, or 20 replicates) and 20 insects/replicate were generated for each of different combinations of  $\pi$  and the degree of variation between replicates **RepVar** = 1. The estimated survival rates of 1000 datasets from using generalized linear models for each true overall survival rate  $\pi$  are presented in Table 11 below.

Table 11: Descriptive statistics of estimated overall survival rates of 1000 datasets per given set of inputs

$\pi$	Nrep	Descriptive statistics of 1000 estimated overall survival rate given RepVar = 1 and 20 insects/replicates				
		Minimum	25th Pctl	50th Pctl	75th Pctl	Maximum
0.05	5	0.000	0.030	0.050	0.060	0.120
	10	0.010	0.040	0.050	0.060	0.100
	15	0.020	0.040	0.050	0.057	0.090
0.1	5	0.010	0.080	0.100	0.120	0.210
	10	0.045	0.085	0.100	0.115	0.165
	15	0.043	0.087	0.100	0.110	0.160
0.2	5	0.080	0.170	0.200	0.230	0.330
	10	0.115	0.180	0.200	0.220	0.300

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$\pi$	Nrep	Descriptive statistics of 1000 estimated overall survival rate given RepVar = 1 and 20 insects/replicates				
		Minimum	25th Pctl	50th Pctl	75th Pctl	Maximum
	15	0.130	0.183	0.200	0.217	0.280
0.5	5	0.310	0.460	0.520	0.570	0.790
	10	0.360	0.475	0.515	0.550	0.715
	15	0.360	0.483	0.513	0.543	0.640
0.8	5	0.590	0.760	0.800	0.850	0.990
	10	0.675	0.770	0.800	0.830	0.940
	15	0.693	0.777	0.800	0.823	0.910
0.9	5	0.000	0.870	0.900	0.930	0.990
	10	0.800	0.875	0.895	0.915	0.980
	15	0.817	0.880	0.897	0.913	0.967
0.95	5	0.000	0.930	0.950	0.970	0.990
	10	0.885	0.935	0.945	0.960	0.995
	15	0.890	0.937	0.947	0.957	0.990

Comments:

- The median of estimated survival rates of 1000 datasets per given set of input  $\pi$ , **NpRep**, and **RepVar** = 1 was very closed to the true overall survival rate  $\pi$ .

### Conclusions

The data generating technique and computer code that generate random data are appropriate because the variation of true survival rate  $\pi_{ij}$ 's of the replicates increases as the input **RepVar** increases and the estimated survival rate of the simulated data is the best estimate of the true overall survival rate  $\pi_I$ .

### SAS code of validation of data generating mechanism



CheckPremise.sas



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## Appendix 2

### SAS code

SAS code for “Validation of data generating technique” (*CheckPremise.sas*)

```
*=====*
* Programmer: James Nguyen, US EPA *
* * *
* Project: Insect Repellency *
* * *
* Study: Power of Premise studies *
* * *
* Purpose: validate the method and the computer code that use to generate *
* random data of Premise studies. If the results are expected, *
* then the method and the computer code that use to generate the *
* random data for power analysis are valid *
* * *
* Assumptions for data generation: *
* - variation of replicates: *
* + overall survival rate is P *
* + median logit of replicate distribution is  $Q = \log(P/(1-P))$  *
* + a random replicate is created by adding a noise to Q *
* * *
* Date: 3/08/2018 *
*=====*;
option formdlim="" nonumber nodate ls=150 ps=200 ;*orientation=landscape;

ods noptitle;
%let junks=C:\Users\JNguyen\Desktop\Junks;

%Macro CheckPremise(P=, RepVar=, NRep=, NPREP=, NSim=, seed=);

  Data Simmer;
    call streaminit(&seed);

    P = &P;
    RepVar = &RepVar;
    NRep = &Nrep;
    NPREP = &NPREP;

    do sim = 1 to &Nsim;
      do rep = 1 to &Nrep;
        Ntotal = &NPREP;

        *==> convert to logit scale;
        if 0 < P < 1 then do;
          Q = Log(P/(1-P));

          *==> add replicate random effect to logit;

          if RepVar > 0 then do;

            *=> shape of weibull distribution;
            a = 1/P;

            *=> location of weibull distribution
            b = exp((1/a)*log(-
              (RepVar**a)/log(0.5)));

            rand = rand("Weibull", a, b) -
              end;
            else if RepVar = 0 then do;
              rand = 0;
            end;

            Qsub = Q + rand;

```

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```

                                **=> convert logit back to probability;
                                PSub = (exp(Qsub))/(1 + exp(Qsub));

                                Nalive = rand("binomial", PSub, NPREP);
                                end;
                                if P = 0 or P = 1 then do;
                                    Nalive = rand("binomial", P, NPREP);
                                end;

                                output;
                                end; *rep;
                                end; *sim;

                                drop Q Qsub;
run;
title;

**=> check the variation of APTSub;
%if &NSim = 1 %then %do;
    Proc means data = Simmer N min p25 p50 p75 max maxdec=3;
        class RepVar P NREp NPREP ;
        var PSub;
    run;
%end;

%if &NSim > 1 %then %do;
    Proc SQL noprint;
        create table Outcome as
            select Sim, sum(Nalive) as Nalive
            from Simmer
            group by Sim
            order by Sim;
    quit;

    Data Outcome1 Outcome2 Outcome3;
        set Outcome;
        if      Nalive = 0          then output outcome1; * "none
alive";
        else if Nalive < &NRep*&NPREP then output outcome2; * "some
alive";
        else if Nalive = &NRep*&NPREP then output outcome3; * "all
alive";
        keep Sim;
    run;

    Proc SQL noprint;
        select count(*) into : NO1      from Outcome1;
        select count(*) into : NO2      from Outcome2;
        select count(*) into : NO3      from Outcome3;
        %let NO1 = &NO1;      %let NO2 = &NO2;      %let NO3 =
&NO3;
    quit;

    %if &NO2 > 0 %then %do;
        Data Outcome2;
            merge Simmer Outcome2(in=mustin);
            by Sim;
            if mustin = 1;
        run;

        ods listing close;      ods select none;
        ods output ParameterEstimates= Obs_P2;*(keep = Sim
estimate Parameter);

        Proc genmod data = Outcome2;
            by Sim;
            model Nalive/Ntotal = /link=logit dist=binomial
dscale;

            run;
            ods select default;      ods listing;

            data Obs_P2;

```

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```
set Obs_P2;
if Parameter="Intercept";
Obs_P = exp(estimate)/(1+exp(estimate));
keep Sim Obs_P ;

run;

%end;

Data Obs_P1;
set outcomel;
Obs_P = 0;

run;

Data Obs_P3;
set outcome3;
Obs_P = 0;

run;

Data All_Obs_P;
set Obs_P1 Obs_P2 Obs_P3;
P = &P;
RepVar = &RepVar;
NRep = &Nrep;
NPREP = &NPREP;

run;

Proc means data = All_Obs_P N min p25 p50 p75 max maxdec=3;
class RepVar P NRep NPREP ;
var Obs_P;

run;

%end;

%Mend;

ods rtf file = "&junks\CheckPremise.rtf" startpage=no bodytitle;
%CheckPremise (P=0.05, RepVar=0, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.10, RepVar=0, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.20, RepVar=0, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.50, RepVar=0, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.80, RepVar=0, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.90, RepVar=0, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.95, RepVar=0, NRep=1000, NPREP=10, NSim=1, seed=1684631);

%CheckPremise (P=0.05, RepVar=0.5, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.10, RepVar=0.5, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.20, RepVar=0.5, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.50, RepVar=0.5, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.80, RepVar=0.5, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.90, RepVar=0.5, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.95, RepVar=0.5, NRep=1000, NPREP=10, NSim=1, seed=1684631);

%CheckPremise (P=0.05, RepVar=1, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.10, RepVar=1, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.20, RepVar=1, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.50, RepVar=1, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.80, RepVar=1, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.90, RepVar=1, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.95, RepVar=1, NRep=1000, NPREP=10, NSim=1, seed=1684631);

%CheckPremise (P=0.05, RepVar=1.5, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.10, RepVar=1.5, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.20, RepVar=1.5, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.50, RepVar=1.5, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.80, RepVar=1.5, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.90, RepVar=1.5, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.95, RepVar=1.5, NRep=1000, NPREP=10, NSim=1, seed=1684631);

%CheckPremise (P=0.05, RepVar=2, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.10, RepVar=2, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.20, RepVar=2, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.50, RepVar=2, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.80, RepVar=2, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.90, RepVar=2, NRep=1000, NPREP=10, NSim=1, seed=1684631);
%CheckPremise (P=0.95, RepVar=2, NRep=1000, NPREP=10, NSim=1, seed=1684631);
```

## Sample Size for Premises Studies Supporting Document

```
ods rtf close;

ods rtf file = "&junks\CheckPremise.rtf" startpage=no bodytitle;
%CheckPremise (P=0.05, RepVar=1, NRep=5, NPRep=20, NSim=1000, seed=168463);
%CheckPremise (P=0.05, RepVar=1, NRep=10, NPRep=20, NSim=1000, seed=168463);
%CheckPremise (P=0.05, RepVar=1, NRep=15, NPRep=20, NSim=1000, seed=168463);

%CheckPremise (P=0.10, RepVar=1, NRep=5, NPRep=20, NSim=1000, seed=168463);
%CheckPremise (P=0.10, RepVar=1, NRep=10, NPRep=20, NSim=1000, seed=168463);
%CheckPremise (P=0.10, RepVar=1, NRep=15, NPRep=20, NSim=1000, seed=168463);

%CheckPremise (P=0.20, RepVar=1, NRep=5, NPRep=20, NSim=1000, seed=168463);
%CheckPremise (P=0.20, RepVar=1, NRep=10, NPRep=20, NSim=1000, seed=168463);
%CheckPremise (P=0.20, RepVar=1, NRep=15, NPRep=20, NSim=1000, seed=168463);

%CheckPremise (P=0.50, RepVar=1, NRep=5, NPRep=20, NSim=1000, seed=168463);
%CheckPremise (P=0.50, RepVar=1, NRep=10, NPRep=20, NSim=1000, seed=168463);
%CheckPremise (P=0.50, RepVar=1, NRep=15, NPRep=20, NSim=1000, seed=168463);

%CheckPremise (P=0.80, RepVar=1, NRep=5, NPRep=20, NSim=1000, seed=168463);
%CheckPremise (P=0.80, RepVar=1, NRep=10, NPRep=20, NSim=1000, seed=168463);
%CheckPremise (P=0.80, RepVar=1, NRep=15, NPRep=20, NSim=1000, seed=168463);

%CheckPremise (P=0.90, RepVar=1, NRep=5, NPRep=20, NSim=1000, seed=168463);
%CheckPremise (P=0.90, RepVar=1, NRep=10, NPRep=20, NSim=1000, seed=168463);
%CheckPremise (P=0.90, RepVar=1, NRep=15, NPRep=20, NSim=1000, seed=168463);

%CheckPremise (P=0.95, RepVar=1, NRep=5, NPRep=20, NSim=1000, seed=168463);
%CheckPremise (P=0.95, RepVar=1, NRep=10, NPRep=20, NSim=1000, seed=168463);
%CheckPremise (P=0.95, RepVar=1, NRep=15, NPRep=20, NSim=1000, seed=168463);
ods rtf close;
```

### SAS code for "Simulations" (*Sample size Premise 2.sas*)

```
*=====*
* Programmer: James Nguyen, US EPA *
* *
* Purpose: Simulations to estimate sample size and power of Premise *
* studies *
* *
* Assumptions for data generation: *
* - variation due to insect *
* - variation of replicates: the degree of variation between *
* replicates in control group is the *
* same as in treatment group *
* - the data generating mechanism is validated by SAS program *
* "CheckPremise.sas" *
* *
* Date: 3/08/2018 *
*=====*;

option formdlim="" nonumber nodate ls=200 ps=200 orientation=landscape;

%let junk=C:\Users\JNguyen\Desktop\Junks;
ods noptitle;

*====> Parameters in Macro:
Nrep = number of replicates/group
NPRep = number of insects/replicate
CP = true survival rate of control group
ATP = true adjusted survival rate of treatment group
ReqCP = required minimum observed survival proportion of control
group
ReqATP = required maximum observed adjusted survival rate of
treatment group
RepVar = degree of variation between replicates
Precision = required maximum precision value
Nsim = number of simulated datasets per scenario
seed = seed to regenerate the results of simulations;
```

## Sample Size for Premises Studies Supporting Document

```
%Macro
Premise (Nrep=, NPRep=, CP=, ATP=, ReqCP=, ReqATP=, RepVar=, Precision=, Nsim=, seed=);

%let N=1;
%let Precision&N = %nrquote(%scan(&Precision,&N, %str( )));
%do %while (&&Precision&N ^=);
    %let N=%eval(&N+1);
    %let Precision&N = %nrquote(%scan(&Precision,&N, %str( )));
%end;
%let N=%eval(&N-1);

title;

Data Simmer;
    call streaminit(&seed);

    *==> true survival probability of control group;
    CP = &CP;

    *==> true survival probability of treatment group;
    TP = &ATP*&CP;

    ATP = &ATP;

    RepVar = &RepVar;
    NRep = &Nrep;
    ReqATP=&ReqATP;

    do sim = 1 to &Nsim;
        do Group = 0 to 1; *0 = Control, 1 = Treatment;

            if Group = 0 then P = CP;
            if Group = 1 then P = TP;

            do rep = 1 to &Nrep;
                Ntotal = &NPRep;

                *==> convert to logit scale;
                if 0 < P < 1 then do;
                    Q = Log(P/(1-P));

                    *==> add replicate random effect to
logit;

                    if RepVar > 0 then do;

                        *=> shape of weibull
distribution;
                        a = 1/P;

                        *=> location of weibull
distribution such median = RepVar;
                        b = exp((1/a)*log(-
(RepVar**a)/log(0.5)));

                        rand = rand("Weibull", a, b)

                    - RepVar;

                    end;
                    else if RepVar = 0 then do;
                        rand = 0;
                    end;

                    Qsub = Q + rand;

                    *==> convert logit back to
probability;
                    PSub = (exp(Qsub))/(1 + exp(Qsub));

                    Nalive = rand("binomial", PSub,
Ntotal);
```

## Sample Size for Premises Studies Supporting Document

```
end;
if P = 0 or P = 1 then do;
    Nalive = rand("binomial", P, Ntotal);
end;

output;
end; *rep;
end; *Group;
end; *sim;

drop Q Qsub a b ;

run;

Proc SQL noprint;
create table Outcome as
select Sim, Group, sum(Nalive) as NAlive
from Simmer
group by Sim, Group
order by Sim, Group;
quit;

Data Outcome;
set Outcome;
if NAlive = 0 then outcome = "none alive";
else if NAlive < &NRep*&NPRep then outcome = "some alive";
else if NAlive = &NRep*&NPRep then outcome = "all alive";

run;

Proc transpose data = outcome out = outcome(drop = _NAME_);
by Sim;
var outcome;
ID group;

run;

Data Outcome1 Outcome2 Outcome3 Outcome4 Outcome5 Outcome6 Outcome7
Outcome8 Outcome9;
merge Outcome;
by Sim;

if _0 = "none alive" and _1 = "none alive" then output Outcome1; /*
Outcome1 = "C none alive - T none alive" */
if _0 = "none alive" and _1 = "some alive" then output Outcome2; /*
Outcome2 = "C none alive - T some alive" */
if _0 = "none alive" and _1 = "all alive" then output Outcome3; /*
Outcome3 = "C none alive - T all alive" */

if _0 = "some alive" and _1 = "none alive" then output Outcome4; /*
Outcome4 = "C some alive - T none alive" */
if _0 = "all alive" and _1 = "none alive" then output Outcome5; /*
Outcome5 = "C all alive - T none alive" */

if _0 = "some alive" and _1 = "some alive" then output Outcome6; /*
Outcome6 = "C some alive - T some alive" */
if _0 = "all alive" and _1 = "some alive" then output Outcome7; /*
Outcome7 = "C all alive - T some alive" */

if _0 = "some alive" and _1 = "all alive" then output Outcome8; /*
Outcome8 = "C some alive - T all alive" */
if _0 = "all alive" and _1 = "all alive" then output Outcome9; /*
Outcome9 = "C all alive - T all alive" */
run;

Proc SQL noprint;
select count(*) into : NO1 from Outcome1; %let NO1 = &NO1;
select count(*) into : NO2 from Outcome2; %let NO2 = &NO2;
select count(*) into : NO3 from Outcome3; %let NO3 = &NO3;
select count(*) into : NO4 from Outcome4; %let NO4 = &NO4;
select count(*) into : NO5 from Outcome5; %let NO5 = &NO5;
select count(*) into : NO6 from Outcome6; %let NO6 = &NO6;
select count(*) into : NO7 from Outcome7; %let NO7 = &NO7;
select count(*) into : NO8 from Outcome8; %let NO8 = &NO8;
```

## Sample Size for Premises Studies Supporting Document

```
select count(*) into : NO9      from Outcome9; %let NO9 = &NO9;
quit;

*==> Outcome = "C some alive - T none alive";

%if &NO4 > 0 %then %do;
  Data Outcome4;
    merge Simmer Outcome4(in=mustin);
    by Sim;
    if Group = 0;
    if mustin = 1;
  run;

ods listing close;      ods select none;
ods output  ParameterEstimates= Obs_CP4(keep = Sim estimate
Parameter);

Proc genmod data = Outcome4;
  by Sim;
  model Nalive/Ntotal = /link=logit dist=binomial dscale;
run;
ods select default;    ods listing;

data Obs_CP4;
  set Obs_CP4;
  if Parameter="Intercept";
  Obs_CP = exp(estimate)/(1+exp(estimate));
run;

Proc SQL noprint;
  *==> number of FAIL datasets because observed CP < 90% ;
  select count(*) into: NO4a
    from Obs_CP4
    where Obs_CP < &ReqCP;
  %let NO4a = &NO4a;

  *==> number of PASS datasets because observed CP >= 90%;
  select count(*) into: NO4b
    from Obs_CP4
    where Obs_CP >= &ReqCP;
  %let NO4b = &NO4b;
quit;

%end;

*==> Outcome6 = "C some alive - T some alive";

%if &NO6 > 0 %then %do;
  Data Outcome6;
    merge Simmer Outcome6(in=mustin);
    by Sim;
    if mustin = 1;
  run;

ods listing close;      ods select none;
ods output  Estimates=Obs_ATP6(keep = Sim MeanEstimate
MeanUpperCL)
              ParameterEstimates= Parameter6(keep = sim
Parameter Level1 estimate);
Proc genmod data = Outcome6;
  by Sim;
  class Group(ref="0");
  model Nalive/Ntotal = Group/link=log dist=binomial dscale
noint;
  estimate  "1 vs. 0" Group 1 -1;
run;
ods select default;    ods listing;

*==> check the observed CP;
data Obs_CP6;
  set Parameter6;
```

## Sample Size for Premises Studies Supporting Document

```

        if Parameter="Group" and Levell = 0;
        Obs_CP = exp(estimate);
        keep Sim Obs_CP;
run;

Proc SQL noprint;
    *====> number of FAIL datasets because observed CP < 90% ;
    select count(*) into: NO6a
        from Obs_CP6
        where Obs_CP < &ReqCP;
    %let NO6a = &NO6a;
quit;

*==> meet condition observed CP >= 90%;
%do NN = 1 %to &N;
    Data Obs_ATP6_&NN;
        merge Obs_CP6 Obs_ATP6;
        by Sim;

        if Obs_CP >= &ReqCP;

        *====> meet observed ATP condition;
        if MeanEstimate <= &ReqATP;

        *====> meet precision condition;
        if MeanUpperCL <= &ReqATP + &&precision&NN;
run;

Proc SQL noprint;
    *====> number of PASSES precision condition;
    select count(*) into: NO6b&NN
        from Obs_ATP6_&NN;
    %let NO6b&NN = &&NO6b&NN;
quit;
%end;
%end;

*==> Outcome7 = "C all alive - T some alive";

%if &NO7 > 0 %then %do;
    Data Outcome7;
        merge Simmer Outcome7(in=mustin);
        by Sim;
        if Group = 1;
        if mustin = 1;
run;

ods listing close;    ods select none;
ods output ParameterEstimates= Obs_ATP7;*(keep = Sim estimate
Parameter);

Proc genmod data = Outcome7;
    by Sim;
    model Nalive/Ntotal = /link=logit dist=binomial dscale;
run;
ods select default;    ods listing;

data Obs_ATP7;
    set Obs_ATP7;
    if Parameter="Intercept";
    Obs_TP = exp(estimate)/(1+exp(estimate));
    UpperWaldCL = exp(UpperWaldCL)/(1+exp(UpperWaldCL));
    keep Sim Obs_TP UpperWaldCL;
run;

%do NN = 1 %to &N;
    Data Obs_ATP7_&NN;
        set Obs_ATP7;

        if Obs_TP <= &ReqATP;

        *====> meet precision condition;

```



## Sample Size for Premises Studies Supporting Document

```

        if UpperWaldCL <= &ReqATP + &&precision&&NN;
run;

Proc SQL noprint;
    *====> number of PASS datasets;
    select count(*) into: NO7&NN
    from Obs_ATP7_&NN;
    %let NO7&NN = &&NO7&NN;
quit;
%end;
%end;

*====> Outcome8 = "C some alive - T all alive";

%if &NO8 > 0 %then %do;
    Data Outcome8;
        merge Simmer Outcome8(in=mustin);
        by Sim;
        if Group = 0;
        if mustin = 1;
run;

ods listing close;    ods select none;
ods output ParameterEstimates= Obs_CP8(keep = Sim estimate
Parameter);

Proc genmod data = Outcome8;
    by Sim;
    model Nalive/Ntotal = /link=logit dist=binomial dscale;
run;
ods select default;    ods listing;

data Obs_CP8;
    set Obs_CP8;
    if Parameter="Intercept";
    Obs_CP = exp(estimate)/(1+exp(estimate));
    keep Sim Obs_CP;
run;

Proc SQL noprint;
    *====> number of FAIL datasets because observed CP < 90% ;
    select count(*) into: NO8a
        from Obs_CP8
        where Obs_CP < &ReqCP;
    %let NO8a = &NO8a;
quit;

%end;

Data Power;
    CP = &CP;
    ATP = &ATP;
    ReqATP=&ReqATP;
    NRep = &Nrep;
    NPRep = &NPRep;

%do NN = 1 %to &N;
    Power&NN = (&NO5
                %if &NO4 > 0 %then %do; + &NO4b %end;
                %if &NO6 > 0 %then %do; + &&NO6b&&NN
                %if &NO7 > 0 %then %do; + &&NO7&&NN
                )/&NSim;
    label Power&NN = "Power at Precision = &&Precision&&NN";
%end;
Control90 = (&NO1 + &NO2 + &NO3
             %if &NO4 > 0 %then %do; + &NO4a %end;
             %if &NO6 > 0 %then %do; + &NO6a %end;
             %if &NO8 > 0 %then %do; + &NO8a %end;
             )/&NSim;

run;

```





















## Sample Size for Premises Studies Supporting Document

```
%Premise(Nrep=10, NPrep=10, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=10, NPrep=15, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=20, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=21, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=22, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=23, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=24, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=25, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=26, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=27, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=28, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=29, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=30, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=31, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=32, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=33, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=34, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=35, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=36, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=37, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=38, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=39, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=40, NPrep=1, ATP=0.05, CP=1, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
ods rtf file = "&junks\Table 7.rtf" bodytitle startpage=no;
Proc print data = AllPower noobs label; format Power: Control90 6.3; run;
ods rtf close;

*====> Table 8;
Data AllPower; set _NULL_ ; run;
%Premise(Nrep=3, NPrep=5, ATP=0.075, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=3, NPrep=10, ATP=0.075, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=3, NPrep=15, ATP=0.075, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=4, NPrep=5, ATP=0.075, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=4, NPrep=10, ATP=0.075, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=4, NPrep=15, ATP=0.075, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=5, NPrep=5, ATP=0.075, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=5, NPrep=10, ATP=0.075, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=5, NPrep=15, ATP=0.075, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
```





## Sample Size for Premises Studies Supporting Document

```
%Premise(Nrep=27, NPrep=1, ATP=0.025, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=28, NPrep=1, ATP=0.025, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=29, NPrep=1, ATP=0.025, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=30, NPrep=1, ATP=0.025, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=31, NPrep=1, ATP=0.025, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=32, NPrep=1, ATP=0.025, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=33, NPrep=1, ATP=0.025, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=34, NPrep=1, ATP=0.025, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=35, NPrep=1, ATP=0.025, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=36, NPrep=1, ATP=0.025, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=37, NPrep=1, ATP=0.025, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=38, NPrep=1, ATP=0.025, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=39, NPrep=1, ATP=0.025, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
%Premise(Nrep=40, NPrep=1, ATP=0.025, CP=0.95, RepVar=1, ReqCP=0.9, ReqATP=0.1,
Precision=0.10 0.15 0.20 0.25, Nsim=1000, seed=274275);
ods rtf file = "&junks\Table 9.rtf" bodytitle startpage=no;
Proc print data = AllPower noobs label; format Power: Control90 6.3; run;
ods rtf close;
```