## **BMA-CRM Simulator version 2.2.4**

#### Model

Target Toxicity Probability	0.300
Safety Stopping Probability (Upper Limit Pr(tox) at Lowest Dose)	0.900
Maximum Sample Size	30
Cohort Size	3
Starting Dose Level	1
Toxicity Assessment Period (Days)	42
Use Data Augmentation (DA)	False

Prior **Median** Probabilities of Toxicity at Each Dose Level:

Prob Set	1
Dose	Prob.
1	0.150
2	0.200
3	0.260
4	0.310
5	0.360

# **Simulation Settings**

Number of Simulated Trials	1000
Random Number Generator Seed	1052
Accrual Rate (Patients per Month)	3.38
Proportion of Toxicities Observed in Second Half of Assessment Period	0.700

### **Scenarios and Results**

Dose Level	True Prob(tox)	<b>Selection Probability</b>	# of Subjects Treated	# of Toxicities
1	0.050	0.00	3.6	0.2
2	0.080	0.00	3.9	0.3
3	0.100	0.01	4.3	0.4
4	0.150	0.06	5.1	0.8

5	0.190	0.93	13.1	2.5			
Probability	Probability of Early Termination: 0.00						
<b>Toxicities p</b>	Toxicities per Trial: 4.2						
Total Trial 1	Time (Months): 1	.7.73					

Scenario: s2

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.300	0.35	14.5	4.3
2	0.350	0.22	6.4	2.3
3	0.370	0.13	3.2	1.2
4	0.450	0.05	1.2	0.6
5	0.550	0.01	0.2	0.1
Probability	Probability of Early Termination: 0.24			

**Toxicities per Trial: 8.4** 

**Total Trial Time (Months):** 16.35

Scenario: s3

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities	
1	0.300	0.34	14.8	4.4	
2	0.330	0.22	6.1	2.0	
3	0.360	0.12	3.2	1.1	
4	0.390	0.06	1.2	0.5	
5	0.420	0.04	0.6	0.3	
Drobobility	Drobability of Early Tormination, 0.22				

**Probability of Early Termination:** 0.23

**Toxicities per Trial: 8.4** 

**Total Trial Time (Months):** 16.56

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities	
1	0.300	0.46	16.3	4.9	
2	0.400	0.23	6.6	2.6	
3	0.500	0.05	2.2	1.1	
4	0.600	0.00	0.3	0.2	
5	0.800	0.00	0.0	0.0	
Probability	Probability of Early Termination: 0.26				

**Toxicities per Trial: 8.8** 

**Total Trial Time (Months):** 16.10

Scenario: s5

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.300	0.56	18.7	5.7
2	0.500	0.14	5.6	2.8
3	0.700	0.01	0.8	0.6
4	0.750	0.00	0.0	0.0
5	0.800	0.00	0.0	0.0

**Probability of Early Termination:** 0.27

**Toxicities per Trial: 9.0** 

Total Trial Time (Months): 15.46

Scenario: s6

Dose Level	True Prob(tox)	<b>Selection Probability</b>	# of Subjects Treated	# of Toxicities
1	0.200	0.22	11.1	2.2
2	0.300	0.36	9.5	3.0
3	0.350	0.22	5.4	1.9
4	0.400	0.11	2.3	0.9
5	0.500	0.04	0.8	0.4

**Probability of Early Termination:** 0.05

**Toxicities per Trial: 8.3** 

Total Trial Time (Months): 19.35

Scenario: s7

Dose Level	True Prob(tox)	<b>Selection Probability</b>	# of Subjects Treated	# of Toxicities
1	0.100	0.14	8.2	0.8
2	0.300	0.60	13.8	4.1
3	0.500	0.22	6.7	3.4
4	0.550	0.02	1.0	0.5
5	0.560	0.00	0.2	0.1

**Probability of Early Termination: 0.01** 

**Toxicities per Trial: 8.9** 

Total Trial Time (Months): 20.42

Scenario: s8

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.050	0.11	6.8	0.3
2	0.300	0.60	14.0	4.1
3	0.450	0.28	7.8	3.6
4	0.700	0.01	1.3	0.9
5	0.780	0.00	0.0	0.0

**Probability of Early Termination: 0.00** 

**Toxicities per Trial: 8.9** 

Total Trial Time (Months): 20.68

Scenario: s9

Dose Level	True Prob(tox)	<b>Selection Probability</b>	# of Subjects Treated	# of Toxicities
1	0.100	0.02	5.0	0.5
2	0.150	0.16	6.9	1.0
3	0.300	0.48	10.6	3.1
4	0.440	0.28	5.8	2.6
5	0.550	0.05	1.7	0.9

**Probability of Early Termination: 0.00** 

**Toxicities per Trial: 8.1** 

Total Trial Time (Months): 20.56

Scenario: s10

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.100	0.01	5.4	0.5
2	0.200	0.20	8.1	1.6
3	0.300	0.43	9.1	2.7
4	0.400	0.24	5.3	2.1
5	0.500	0.11	2.1	1.0

**Probability of Early Termination:** 0.00

**Toxicities per Trial:** 7.9

Total Trial Time (Months): 20.52

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.050	0.01	4.6	0.2
2	0.200	0.21	8.5	1.7
3	0.300	0.44	9.5	2.8
4	0.400	0.28	5.6	2.3
5	0.600	0.06	1.9	1.2

**Probability of Early Termination: 0.00** 

**Toxicities per Trial:** 8.2

Total Trial Time (Months): 20.59

Scenario: s12

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.280	0.25	12.8	3.5
2	0.290	0.21	6.4	1.9
3	0.300	0.14	4.2	1.3
4	0.310	0.11	2.0	0.6
5	0.320	0.13	1.6	0.5

**Probability of Early Termination:** 0.15

**Toxicities per Trial:** 7.8

**Total Trial Time (Months): 17.70** 

Scenario: s13

Dose Level	True Prob(tox)	<b>Selection Probability</b>	# of Subjects Treated	# of Toxicities
1	0.150	0.08	7.9	1.2
2	0.250	0.27	8.6	2.1
3	0.300	0.30	6.9	2.1
4	0.350	0.26	4.3	1.5
5	0.550	0.08	1.9	1.0

**Probability of Early Termination:** 0.02

**Toxicities per Trial:** 7.9

**Total Trial Time (Months): 20.06** 

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities

1	0.050	0.00	3.7	0.2
2	0.080	0.01	4.2	0.4
3	0.120	0.21	6.1	0.7
4	0.300	0.55	9.9	2.9
5	0.600	0.23	6.2	3.7

**Probability of Early Termination: 0.00** 

**Toxicities per Trial:** 7.9

**Total Trial Time (Months):** 19.92

Scenario: s15

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.120	0.01	5.1	0.6
2	0.140	0.06	5.5	0.8
3	0.200	0.20	6.9	1.3
4	0.300	0.35	7.0	2.1
5	0.400	0.38	5.4	2.2

**Probability of Early Termination:** 0.00

**Toxicities per Trial:** 7.0

**Total Trial Time (Months): 20.01** 

Scenario: s16

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.050	0.00	3.6	0.2
2	0.060	0.01	3.8	0.2
3	0.070	0.23	5.9	0.4
4	0.300	0.67	11.8	3.5
5	0.800	0.09	4.9	3.9

**Probability of Early Termination: 0.00** 

**Toxicities per Trial: 8.3** 

**Total Trial Time (Months): 19.87** 

Scenario: s17

Dose LevelTrue Prob(tox)Selection Probability# of Subjects Treated# of Toxicities10.2500.2011.52.920.2600.206.61.7

3	0.270	0.18	4.8	1.3
4	0.300	0.15	2.9	0.9
5	0.330	0.17	2.1	0.7

**Probability of Early Termination:** 0.10

**Toxicities per Trial:** 7.5

**Total Trial Time (Months):** 18.26

Scenario: s18

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.050	0.00	3.7	0.2
2	0.100	0.01	4.5	0.5
3	0.150	0.04	5.2	0.7
4	0.190	0.17	5.9	1.1
5	0.300	0.78	10.7	3.2

**Probability of Early Termination: 0.00** 

**Toxicities per Trial:** 5.7

**Total Trial Time (Months): 18.72** 

Scenario: s19

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.300	0.38	14.8	4.4
2	0.350	0.24	6.6	2.4
3	0.400	0.11	3.2	1.3
4	0.450	0.03	0.9	0.4
5	0.700	0.00	0.1	0.1

**Probability of Early Termination:** 0.23

**Toxicities per Trial: 8.6** 

**Total Trial Time (Months): 16.46** 

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.300	0.32	13.7	4.1
2	0.310	0.25	6.9	2.1
3	0.400	0.16	4.0	1.6
4	0.500	0.04	1.1	0.6

5	0.600	0.01	0.2	0.1				
<b>Probability of Early Termination:</b> 0.22								
Toxicities per Trial: 8.5								
Total Trial Time (Months): 16.74								

Elapsed time: 1 minutes, 29 seconds

## **BMA-CRM BackEnd version 2.2.4**

Report time: Tuesday, April 9, 2019 9:12:41 PM