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

### Model

Target Toxicity Probability	0.200
Safety Stopping Probability (Upper Limit Pr(tox) at Lowest Dose)	0.900
Maximum Sample Size	18
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

# **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**

**Scenario: All Below Target** 

Dose Level	True Prob(tox)	<b>Selection Probability</b>	# of Subjects Treated	# of Toxicities
1	0.050	0.06	4.7	0.2
2	0.100	0.16	4.3	0.4
3	0.150	0.77	8.9	1.3

**Probability of Early Termination:** 0.01

**Toxicities per Trial:** 2.0

Total Trial Time (Months): 12.34

Scenario: Target @ 1

Dose Level	True Prob(tox)	<b>Selection Probability</b>	# of Subjects Treated	# of Toxicities
1	0.200	0.40	9.4	1.9
2	0.250	0.21	3.4	0.8
3	0.300	0.15	2.5	0.8

**Probability of Early Termination: 0.22** 

**Toxicities per Trial:** 3.5

**Total Trial Time (Months):** 10.36

Scenario: Target @ 1 v2

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.200	0.56	11.1	2.2
2	0.400	0.15	3.3	1.3
3	0.600	0.00	0.8	0.5

**Probability of Early Termination: 0.25** 

**Toxicities per Trial: 4.0** 

**Total Trial Time (Months):** 10.19

Scenario: Target @ 2

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.100	0.28	7.7	0.7
2	0.200	0.38	5.2	1.0
3	0.300	0.29	4.5	1.4

**Probability of Early Termination: 0.05** 

**Toxicities per Trial:** 3.2

Total Trial Time (Months): 11.98

Scenario: Target @ 2 v2

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.050	0.38	8.2	0.4
2	0.200	0.50	6.4	1.3
3	0.600	0.10	3.2	1.9

**Probability of Early Termination: 0.02** 

Toxicities per Trial: 3.6

**Total Trial Time (Months):** 12.23

Scenario: Target @ 3

Dose Level	True Prob(tox)	<b>Selection Probability</b>	# of Subjects Treated	# of Toxicities
1	0.100	0.16	6.7	0.6
2	0.150	0.29	4.6	0.7
3	0.200	0.51	6.2	1.3

**Probability of Early Termination:** 0.04

**Toxicities per Trial: 2.6** 

Total Trial Time (Months): 12.02

Scenario: Target @ 3 v2

Dose Level	True Prob(tox)	<b>Selection Probability</b>	# of Subjects Treated	# of Toxicities
1	0.050	0.07	5.0	0.3
2	0.100	0.23	4.6	0.4
3	0.200	0.70	8.3	1.7

**Probability of Early Termination: 0.01** 

**Toxicities per Trial: 2.4** 

**Total Trial Time (Months):** 12.41

Scenario: All above Target

Dose Level	True Prob(tox)	<b>Selection Probability</b>	# of Subjects Treated	# of Toxicities
1	0.250	0.42	9.9	2.5
2	0.300	0.14	2.8	0.8
3	0.400	0.06	1.4	0.6

**Probability of Early Termination: 0.33** 

**Toxicities per Trial: 3.8** 

**Total Trial Time (Months):** 9.45

Scenario: All above target v2

Dose Level	True Prob(tox)	<b>Selection Probability</b>	# of Subjects Treated	# of Toxicities
1	0.400	0.16	7.6	3.1
2	0.500	0.01	1.1	0.5
3	0.600	0.00	0.2	0.1

**Probability of Early Termination:** 0.78

**Toxicities per Trial: 3.8** 

Total Trial Time (Months): 5.90

Scenario: All Well Above Target

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.500	0.04	6.0	3.0
2	0.600	0.00	0.5	0.3
3	0.700	0.00	0.0	0.0

**Probability of Early Termination: 0.92** 

**Toxicities per Trial: 3.3** 

**Total Trial Time (Months): 4.27** 

Elapsed time: 15 seconds

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

Report time: Tuesday, April 9, 2019 7:38:19 PM