### **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	1
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	0.05	3.2	0.2
2	0.100	0.14	2.9	0.3
3	0.150	0.75	10.9	1.6

**Probability of Early Termination:** 0.06

**Toxicities per Trial: 2.1** 

**Total Trial Time (Months):** 21.22

Scenario: Target @ 1

Dose Level	True Prob(tox)	<b>Selection Probability</b>	# of Subjects Treated	# of Toxicities
1	0.200	0.31	6.2	1.2
2	0.250	0.13	2.6	0.7
3	0.300	0.19	4.1	1.2

**Probability of Early Termination: 0.37** 

**Toxicities per Trial: 3.1** 

**Total Trial Time (Months):** 15.69

Scenario: Target @ 1 v2

Dose Level	True Prob(tox)	<b>Selection Probability</b>	# of Subjects Treated	# of Toxicities
1	0.200	0.43	8.4	1.7
2	0.400	0.09	2.3	0.9
3	0.600	0.01	1.1	0.7

**Probability of Early Termination: 0.46** 

**Toxicities per Trial: 3.3** 

Total Trial Time (Months): 13.18

Scenario: Target @ 2

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.100	0.27	6.1	0.6
2	0.200	0.29	4.0	0.8
3	0.300	0.28	5.4	1.6

**Probability of Early Termination: 0.16** 

**Toxicities per Trial: 3.1** 

**Total Trial Time (Months): 19.68** 

Scenario: Target @ 2 v2

Dose Level	True Prob(tox)	<b>Selection Probability</b>	# of Subjects Treated	# of Toxicities
1	0.050	0.36	7.7	0.4
2	0.200	0.45	6.2	1.2
3	0.600	0.12	3.0	1.8

**Probability of Early Termination: 0.07** 

Toxicities per Trial: 3.4

**Total Trial Time (Months):** 21.91

Scenario: Target @ 3

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.100	0.15	4.1	0.4
2	0.150	0.17	3.3	0.5
3	0.200	0.54	8.3	1.7

**Probability of Early Termination:** 0.14

**Toxicities per Trial: 2.6** 

Total Trial Time (Months): 20.04

Scenario: Target @ 3 v2

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.050	0.07	3.4	0.2
2	0.100	0.20	3.5	0.3
3	0.200	0.66	10.0	2.0

**Probability of Early Termination: 0.07** 

**Toxicities per Trial: 2.5** 

Total Trial Time (Months): 21.90

Scenario: All above Target

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.250	0.32	6.4	1.6
2	0.300	0.10	2.3	0.7
3	0.400	0.07	2.5	1.0

**Probability of Early Termination:** 0.51

**Toxicities per Trial:** 3.2

Total Trial Time (Months): 13.27

Scenario: All above target v2

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.400	0.11	4.8	1.9
2	0.500	0.01	0.9	0.4
3	0.600	0.00	0.6	0.4

**Probability of Early Termination:** 0.88

**Toxicities per Trial: 2.7** 

Total Trial Time (Months): 7.00

Scenario: All Well Above Target

Dose Level	True Prob(tox)	<b>Selection Probability</b>	# of Subjects Treated	# of Toxicities
1	0.500	0.03	3.3	1.6
2	0.600	0.00	0.6	0.4
3	0.700	0.00	0.3	0.2

**Probability of Early Termination: 0.97** 

**Toxicities per Trial: 2.2** 

**Total Trial Time (Months): 4.72** 

Elapsed time: 39 seconds

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

Report time: Tuesday, April 9, 2019 7:30:57 PM