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	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)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.050	0.01	4.6	0.2
2	0.080	0.05	4.9	0.4
3	0.100	0.13	5.4	0.6
4	0.150	0.20	5.5	0.8

5	0.190	0.60	9.4	1.8			
Probability	Probability of Early Termination: 0.01						
Toxicities per Trial: 3.7							
Total Trial 1	Time (Months): 2	20.38					

Scenario: s2

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities	
1	0.200	0.37	13.8	2.7	
2	0.250	0.17	5.3	1.3	
3	0.260	0.09	2.9	0.7	
4	0.270	0.05	1.5	0.4	
5	0.290	0.04	1.0	0.3	
Probability	Probability of Early Termination: 0.26				
Toxicities p	Toxicities per Trial: 5.5				
Total Trial	Total Trial Time (Months): 16.25				

Scenario: s3

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities	
1	0.200	0.45	15.0	3.0	
2	0.300	0.17	5.8	1.7	
3	0.300	0.06	2.3	0.7	
4	0.450	0.01	0.8	0.4	
5	0.500	0.00	0.2	0.1	
Probability	Probability of Early Termination: 0.30				
Toxicities per Trial: 5.9					
Total Trial Time (Months): 15.73					

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.200	0.31	13.0	2.6
2	0.210	0.16	5.1	1.1
3	0.220	0.11	3.4	0.7
4	0.230	0.08	1.9	0.5
5	0.240	0.10	1.8	0.4
Probability of Early Termination: 0.23				

Toxicities per Trial: 5.3

Total Trial Time (Months): 17.00

Scenario: s5

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.200	0.50	16.3	3.2
2	0.300	0.18	5.6	1.7
3	0.500	0.02	1.8	0.9
4	0.550	0.00	0.3	0.1
5	0.600	0.00	0.0	0.0

Probability of Early Termination: 0.30

Toxicities per Trial: 5.9

Total Trial Time (Months): 15.60

Scenario: s6

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.190	0.29	12.4	2.3
2	0.200	0.18	5.5	1.1
3	0.230	0.14	3.8	0.8
4	0.250	0.09	2.2	0.6
5	0.300	0.08	1.7	0.5

Probability of Early Termination: 0.21

Toxicities per Trial: 5.4

Total Trial Time (Months): 17.33

Scenario: s7

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.100	0.29	11.5	1.2
2	0.200	0.47	10.0	2.0
3	0.330	0.17	5.4	1.8
4	0.450	0.02	1.5	0.7
5	0.550	0.00	0.2	0.1

Probability of Early Termination: 0.06

Toxicities per Trial: 5.8

Total Trial Time (Months): 19.45

Scenario: s8

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.050	0.24	10.3	0.5
2	0.200	0.56	12.1	2.5
3	0.400	0.16	5.7	2.3
4	0.500	0.01	1.1	0.5
5	0.560	0.00	0.2	0.1

Probability of Early Termination: 0.02

Toxicities per Trial: 5.9

Total Trial Time (Months): 20.19

Scenario: s9

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.100	0.13	8.6	0.9
2	0.150	0.27	7.5	1.1
3	0.200	0.27	6.0	1.2
4	0.250	0.15	3.7	1.0
5	0.300	0.14	3.2	0.9

Probability of Early Termination: 0.04

Toxicities per Trial: 5.1

Total Trial Time (Months): 19.94

Scenario: s10

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.100	0.20	9.6	1.0
2	0.190	0.35	8.5	1.6
3	0.200	0.29	6.4	1.3
4	0.400	0.11	3.2	1.3
5	0.500	0.01	0.9	0.5
Probability of Early Termination: 0.06				

Toxicities per Trial: 5.6

Total Trial Time (Months): 19.71

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.050	0.09	7.0	0.4
2	0.150	0.35	9.3	1.4
3	0.200	0.39	8.1	1.6
4	0.400	0.14	4.1	1.7
5	0.450	0.02	1.2	0.5

Probability of Early Termination: 0.01

Toxicities per Trial: 5.6

Total Trial Time (Months): 20.88

Scenario: s12

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.180	0.27	12.1	2.2
2	0.190	0.16	5.4	1.0
3	0.200	0.16	4.1	0.8
4	0.240	0.12	2.5	0.6
5	0.260	0.11	2.0	0.5

Probability of Early Termination: 0.18

Toxicities per Trial: 5.1

Total Trial Time (Months): 17.73

Scenario: s13

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.050	0.05	6.1	0.3
2	0.120	0.28	7.8	1.0
3	0.200	0.38	8.2	1.7
4	0.300	0.21	4.9	1.5
5	0.400	0.07	2.6	1.0

Probability of Early Termination: 0.01

Toxicities per Trial: 5.4

Total Trial Time (Months): 20.93

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

1	0.050	0.01	4.5	0.2
2	0.080	0.07	5.0	0.4
3	0.120	0.19	6.5	0.8
4	0.200	0.29	6.2	1.3
5	0.220	0.43	7.6	1.7

Probability of Early Termination: 0.01

Toxicities per Trial: 4.3

Total Trial Time (Months): 20.66

Scenario: s15

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.120	0.11	8.8	1.1
2	0.140	0.19	6.0	0.9
3	0.160	0.17	4.8	0.7
4	0.200	0.18	4.0	0.8
5	0.220	0.28	4.5	1.0

Probability of Early Termination: 0.08

Toxicities per Trial: 4.5

Total Trial Time (Months): 19.21

Scenario: s16

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.050	0.00	4.4	0.2
2	0.060	0.04	4.6	0.3
3	0.070	0.28	6.7	0.5
4	0.200	0.47	8.3	1.7
5	0.400	0.20	5.8	2.4

Probability of Early Termination: 0.01

Toxicities per Trial: 5.1

Total Trial Time (Months): 21.05

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.050	0.02	5.0	0.2
2	0.070	0.21	6.7	0.5

3	0.180	0.47	9.9	1.7
4	0.200	0.27	5.8	1.1
5	0.800	0.03	2.5	2.0

Probability of Early Termination: 0.01

Toxicities per Trial: 5.5

Total Trial Time (Months): 21.16

Scenario: s18

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.050	0.02	5.2	0.2
2	0.100	0.13	6.0	0.6
3	0.150	0.18	6.2	0.9
4	0.190	0.22	5.2	1.0
5	0.200	0.44	7.3	1.5

Probability of Early Termination: 0.01

Toxicities per Trial: 4.2

Total Trial Time (Months): 20.67

Scenario: s19

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.200	0.38	13.9	2.8
2	0.250	0.19	5.5	1.4
3	0.280	0.10	3.0	0.9
4	0.300	0.04	1.5	0.5
5	0.350	0.02	0.7	0.3

Probability of Early Termination: 0.26

Toxicities per Trial: 5.7

Total Trial Time (Months): 16.33

Dose Level	True Prob(tox)	Selection Probability	# of Subjects Treated	# of Toxicities
1	0.250	0.40	14.7	3.7
2	0.300	0.09	4.1	1.2
3	0.400	0.02	1.7	0.7
4	0.500	0.00	0.4	0.2

5	0.600	0.00	0.1	0.0				
Probability of Early Termination: 0.47								
Toxicities per Trial: 5.8								
Total Trial Time (Months): 13.65								

Elapsed time: 1 minutes, 36 seconds

BMA-CRM BackEnd version 2.2.4

Report time: Tuesday, April 9, 2019 9:02:26 PM