

BMA-CRM Simulator version 2.2.4

Model

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|--|-------|
| Target Toxicity Probability | 0.300 |
| Safety Stopping Probability (Upper Limit $Pr(\text{tox})$ 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: s1

| Dose Level | True Prob(tox) | Selection Probability | # of Subjects Treated | # of Toxicities |
|---|----------------|-----------------------|-----------------------|-----------------|
| 1 | 0.050 | 0.00 | 3.7 | 0.2 |
| 2 | 0.100 | 0.05 | 4.2 | 0.4 |
| 3 | 0.150 | 0.95 | 10.1 | 1.5 |
| Probability of Early Termination: 0.00 | | | | |
| Toxicities per Trial: 2.2 | | | | |
| Total Trial Time (Months): 11.11 | | | | |

Scenario: s2

| Dose Level | True Prob(tox) | Selection Probability | # of Subjects Treated | # of Toxicities |
|---|----------------|-----------------------|-----------------------|-----------------|
| 1 | 0.300 | 0.49 | 10.6 | 3.2 |
| 2 | 0.400 | 0.23 | 4.2 | 1.6 |
| 3 | 0.500 | 0.09 | 1.5 | 0.8 |
| Probability of Early Termination: 0.19 | | | | |
| Toxicities per Trial: 5.6 | | | | |
| Total Trial Time (Months): 10.73 | | | | |

Scenario: s3

| Dose Level | True Prob(tox) | Selection Probability | # of Subjects Treated | # of Toxicities |
|---|----------------|-----------------------|-----------------------|-----------------|
| 1 | 0.300 | 0.64 | 12.3 | 3.7 |
| 2 | 0.600 | 0.12 | 3.6 | 2.1 |
| 3 | 0.700 | 0.01 | 0.3 | 0.2 |
| Probability of Early Termination: 0.21 | | | | |
| Toxicities per Trial: 6.0 | | | | |
| Total Trial Time (Months): 10.44 | | | | |

Scenario: s4

| Dose Level | True Prob(tox) | Selection Probability | # of Subjects Treated | # of Toxicities |
|---|----------------|-----------------------|-----------------------|-----------------|
| 1 | 0.050 | 0.23 | 6.0 | 0.3 |
| 2 | 0.300 | 0.64 | 8.3 | 2.5 |
| 3 | 0.700 | 0.13 | 3.7 | 2.6 |
| Probability of Early Termination: 0.00 | | | | |
| Toxicities per Trial: 5.3 | | | | |
| Total Trial Time (Months): 12.20 | | | | |

Scenario: s5

| Dose Level | True Prob(tox) | Selection Probability | # of Subjects Treated | # of Toxicities |
|---|----------------|-----------------------|-----------------------|-----------------|
| 1 | 0.200 | 0.32 | 8.4 | 1.7 |
| 2 | 0.300 | 0.32 | 5.3 | 1.6 |
| 3 | 0.400 | 0.31 | 3.8 | 1.6 |
| Probability of Early Termination: 0.05 | | | | |
| Toxicities per Trial: 4.9 | | | | |

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| Total Trial Time (Months): 11.61 |
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Scenario: s6

| Dose Level | True Prob(tox) | Selection Probability | # of Subjects Treated | # of Toxicities |
|---|----------------|-----------------------|-----------------------|-----------------|
| 1 | 0.100 | 0.06 | 5.1 | 0.5 |
| 2 | 0.200 | 0.26 | 5.6 | 1.1 |
| 3 | 0.300 | 0.68 | 7.2 | 2.2 |
| Probability of Early Termination: 0.00 | | | | |
| Toxicities per Trial: 3.8 | | | | |
| Total Trial Time (Months): 11.77 | | | | |

Scenario: s7

| Dose Level | True Prob(tox) | Selection Probability | # of Subjects Treated | # of Toxicities |
|---|----------------|-----------------------|-----------------------|-----------------|
| 1 | 0.050 | 0.01 | 3.7 | 0.2 |
| 2 | 0.080 | 0.11 | 4.2 | 0.3 |
| 3 | 0.300 | 0.88 | 10.0 | 3.0 |
| Probability of Early Termination: 0.00 | | | | |
| Toxicities per Trial: 3.6 | | | | |
| Total Trial Time (Months): 11.41 | | | | |

Scenario: s8

| Dose Level | True Prob(tox) | Selection Probability | # of Subjects Treated | # of Toxicities |
|---|----------------|-----------------------|-----------------------|-----------------|
| 1 | 0.400 | 0.43 | 11.0 | 4.5 |
| 2 | 0.500 | 0.06 | 2.2 | 1.1 |
| 3 | 0.600 | 0.01 | 0.4 | 0.2 |
| Probability of Early Termination: 0.47 | | | | |
| Toxicities per Trial: 5.8 | | | | |
| Total Trial Time (Months): 8.73 | | | | |

Scenario: s9

| Dose Level | True Prob(tox) | Selection Probability | # of Subjects Treated | # of Toxicities |
|---|----------------|-----------------------|-----------------------|-----------------|
| 1 | 0.500 | 0.23 | 9.8 | 4.9 |
| 2 | 0.600 | 0.01 | 1.0 | 0.6 |
| 3 | 0.700 | 0.00 | 0.1 | 0.1 |
| Probability of Early Termination: 0.73 | | | | |

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| Toxicities per Trial: 5.5 |
| Total Trial Time (Months): 6.85 |

Scenario: s10

| Dose Level | True Prob(tox) | Selection Probability | # of Subjects Treated | # of Toxicities |
|---|-----------------------|------------------------------|------------------------------|------------------------|
| 1 | 0.700 | 0.01 | 6.1 | 4.2 |
| 2 | 0.800 | 0.00 | 0.1 | 0.1 |
| 3 | 0.900 | 0.00 | 0.0 | 0.0 |
| Probability of Early Termination: 0.99 | | | | |
| Toxicities per Trial: 4.3 | | | | |
| Total Trial Time (Months): 3.75 | | | | |

Elapsed time: 13 seconds

BMA-CRM BackEnd version 2.2.4

Report time: Tuesday, April 9, 2019 10:14:47 PM