BOIN Simulation Report

Bayesian Optimal Interval (BOIN) Phase I Design (PID-862) Version: 1.0.7
Tuesday, April 9, 2019 7:49:48 PM (GMT -05:00:00)

Trial and Model Specifications

Parameter	Value
Number of doses	3
Starting dose	1
Max sample size	18
Cohort size	1
Stop trial if # patients assigned to single dose reaches	15
Use accelerated titration	False
Target toxicity probability	0.2
Alternative (unacceptable high toxicity) for optimization	0.28
Alternative (unacceptable low toxicity) for optimization	0.12
Eliminate dose threshold (pE)	0.95
Number of repetitions	1000
Random number generator seed	22

Operating Characteristics

	Dose Level			Number of Patients	% Early Stopping
	1	**2**	**3**		
All Below Target					
True DLT Rate	0.05	0.10	0.15		
Selection %	4.7	19.6	75.2		0.5
# Pts Treated	2.5	4.4	10.7	17.55	
Target @1					
True DLT Rate	0.20	0.25	0.30		
Selection %	36.2	27.5	20.6		15.7
# Pts Treated	6.5	4.9	4.6	16.00	
Target @ 1 v2					

True DLT Rate	0.20	0.40	0.60		
Selection %	64.2	17.0	0.5		18.3
# Pts Treated	9.8	4.6	1.5	15.84	

Target @ 2

True DLT Rate	0.10	0.20	0.30		
Selection %	25.9	42.3	28.2		3.6
# Pts Treated	5.3	6.3	5.7	17.42	

Target @ 2 v2

True DLT Rate	0.05	0.20	0.60		
Selection %	25.5	71.6	2.3		0.6
# Pts Treated	5.5	9.3	3.1	17.91	

Target @ 3

True DLT Rate	0.10	0.15	0.20		
Selection %	14.9	28.8	52.6		3.7
# Pts Treated	4.0	5.2	8.1	17.27	

Target @ 3 v2

True DLT Rate	0.05	0.10	0.20		
Selection %	4.5	31.1	64.2		0.2
# Pts Treated	2.5	5.7	9.5	17.72	

All Above Target

True DLT Rate	0.25	0.30	0.40		
Selection %	43.4	22.4	6.8		27.4
# Pts Treated	7.4	4.5	2.8	14.72	

All Above Target v2

True DLT Rate	0.40	0.50	0.60		
Selection %	26.9	1.9	0.1		71.1
# Pts Treated	7.7	2.1	0.8	10.57	

All Well Above Target

True DLT Rate	0.50	0.60	0.70		

Selection %	8.5	0.8	0.0			90.7
# Pts Treated	5.9	1.3	0.4	7.66		