

# BOIN Simulation Report

Bayesian Optimal Interval (BOIN) Phase I Design (PID-862) Version: 1.0.7  
 Tuesday, April 9, 2019 10:07:43 PM (GMT -05:00:00)

## Trial and Model Specifications

Parameter	Value
Number of doses	5
Starting dose	1
Max sample size	30
Cohort size	3
Stop trial if # patients assigned to single dose reaches	24
Use accelerated titration	False
Target toxicity probability	0.3
Alternative (unacceptable high toxicity) for optimization	0.42
Alternative (unacceptable low toxicity) for optimization	0.18
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	4	5		
<u>s1</u>							
True DLT Rate	0.05	0.08	0.10	0.15	0.19		
Selection %	0.0	0.8	3.3	13.7	82.2		0.0
# Pts Treated	3.6	4.2	4.8	5.6	11.7	30.00	
<u>s2</u>							
True DLT Rate	0.30	0.35	0.37	0.45	0.55		
Selection %	50.1	19.2	8.9	4.0	1.0		16.8
# Pts Treated	14.6	6.7	2.5	0.9	0.2	24.95	
<u>s3</u>							

<b>True DLT Rate</b>	0.30	0.33	0.36	0.39	0.42	
<b>Selection %</b>	44.9	20.8	11.3	3.9	2.2	16.9
<b># Pts Treated</b>	14.1	6.7	2.8	1.0	0.4	24.98
<b><u>s4</u></b>						
<b>True DLT Rate</b>	0.30	0.40	0.50	0.60	0.80	
<b>Selection %</b>	58.6	19.1	4.6	0.2	0.0	17.5
<b># Pts Treated</b>	16.1	6.7	1.8	0.3	0.0	24.86
<b><u>s5</u></b>						
<b>True DLT Rate</b>	0.30	0.50	0.70	0.75	0.80	
<b>Selection %</b>	72.2	10.1	0.1	0.0	0.0	17.6
<b># Pts Treated</b>	18.2	6.0	0.5	0.0	0.0	24.74
<b><u>s6</u></b>						
<b>True DLT Rate</b>	0.20	0.30	0.35	0.40	0.50	
<b>Selection %</b>	29.0	38.0	17.8	9.4	2.6	3.2
<b># Pts Treated</b>	11.1	10.2	4.8	1.8	0.6	28.56
<b><u>s7</u></b>						
<b>True DLT Rate</b>	0.10	0.30	0.50	0.55	0.56	
<b>Selection %</b>	17.4	69.5	11.4	1.4	0.0	0.3
<b># Pts Treated</b>	8.9	15.0	5.1	0.7	0.1	29.71
<b><u>s8</u></b>						
<b>True DLT Rate</b>	0.05	0.30	0.45	0.70	0.78	
<b>Selection %</b>	14.7	66.2	18.9	0.1	0.0	0.1
<b># Pts Treated</b>	7.9	14.9	6.2	0.8	0.0	29.84
<b><u>s9</u></b>						
<b>True DLT Rate</b>	0.10	0.15	0.30	0.44	0.55	
<b>Selection %</b>	2.5	21.0	54.6	19.6	2.1	0.2
<b># Pts Treated</b>	5.1	8.8	10.7	4.5	0.7	29.87
<b><u>s10</u></b>						
<b>True DLT Rate</b>	0.10	0.20	0.30	0.40	0.50	

<b>Selection %</b>	6.4	30.0	39.2	20.8	3.6		0.0
<b># Pts Treated</b>	6.0	9.8	8.8	4.2	1.1	29.87	
<b><u>s11</u></b>							
<b>True DLT Rate</b>	0.05	0.20	0.30	0.40	0.60		
<b>Selection %</b>	4.1	29.3	42.8	22.0	1.8		0.0
<b># Pts Treated</b>	5.2	10.0	9.2	4.5	1.0	29.91	
<b><u>s12</u></b>							
<b>True DLT Rate</b>	0.28	0.29	0.30	0.31	0.32		
<b>Selection %</b>	37.6	18.8	14.0	8.3	7.5		13.8
<b># Pts Treated</b>	12.8	6.5	3.7	1.6	1.0	25.64	
<b><u>s13</u></b>							
<b>True DLT Rate</b>	0.15	0.25	0.30	0.35	0.55		
<b>Selection %</b>	15.9	31.3	27.4	20.6	3.6		1.2
<b># Pts Treated</b>	8.4	9.9	6.5	3.5	1.0	29.34	
<b><u>s14</u></b>							
<b>True DLT Rate</b>	0.05	0.08	0.12	0.30	0.60		
<b>Selection %</b>	0.0	0.9	21.9	69.5	7.7		0.0
<b># Pts Treated</b>	3.6	4.4	7.6	11.0	3.4	30.00	
<b><u>s15</u></b>							
<b>True DLT Rate</b>	0.12	0.14	0.20	0.30	0.40		
<b>Selection %</b>	3.0	9.0	27.5	39.9	20.2		0.4
<b># Pts Treated</b>	5.5	6.2	7.9	6.8	3.5	29.77	
<b><u>s16</u></b>							
<b>True DLT Rate</b>	0.05	0.06	0.07	0.30	0.80		
<b>Selection %</b>	0.0	0.4	16.1	82.8	0.7		0.0
<b># Pts Treated</b>	3.5	3.9	6.8	13.2	2.6	30.00	
<b><u>s17</u></b>							
<b>True DLT Rate</b>	0.25	0.26	0.27	0.30	0.33		
<b>Selection %</b>	32.1	17.0	18.4	14.1	10.4		8.0

<b># Pts Treated</b>	11.5	7.2	4.5	2.5	1.5	27.08
<b><u>s18</u></b>						
<b>True DLT Rate</b>	0.05	0.10	0.15	0.19	0.30	
<b>Selection %</b>	0.0	2.5	10.3	32.3	54.9	0.0
<b># Pts Treated</b>	3.7	5.1	6.2	6.9	8.1	29.99
<b><u>s19</u></b>						
<b>True DLT Rate</b>	0.30	0.35	0.40	0.45	0.70	
<b>Selection %</b>	50.4	21.4	7.2	4.1	0.1	16.8
<b># Pts Treated</b>	14.6	7.0	2.4	0.8	0.2	24.95
<b><u>s20</u></b>						
<b>True DLT Rate</b>	0.30	0.31	0.40	0.50	0.60	
<b>Selection %</b>	41.0	26.6	12.1	3.1	0.4	16.8
<b># Pts Treated</b>	13.4	7.3	3.4	0.8	0.1	25.06