Bayesian Efficacy Monitoring Via Predictive Probability v1.1.3.0
Date/Time generated: 2022−07−12 01:44:18 US Central Time

Stopping Boundaries Input

Input Parameter	Input Value
Trial Name (Optional)	EISAI
Reference response rate (theta0)	0.2
Threshold for declaring efficacy at the end of the trial (pT)	0.95
Early Stopping for Futility	TRUE
Probability confidence threshold for futility stopping (pL)	0.025
Early Stopping for Efficacy	TRUE
Probability confidence threshold for declaring efficacy early (pU)	0.99
Prior distribution for theta:Beta(a0,b0) a0	0.2
Prior distribution for theta:Beta(a0,b0) b0	0.8
Input Cohort Manually	FALSE
Maximum number of patients in the trial	100
Minimum number of patients before early stopping rule applies	38
Cohort size	1
Cohorts for interim analysis	

Table 1A: Probability of Futility Early Stopping

Number of Responses

(Highlighted = Predictive Probability (PP) < 0.025, where PP = Sum(Prob(θ > 0.2) >= 0.95 | current and future data))

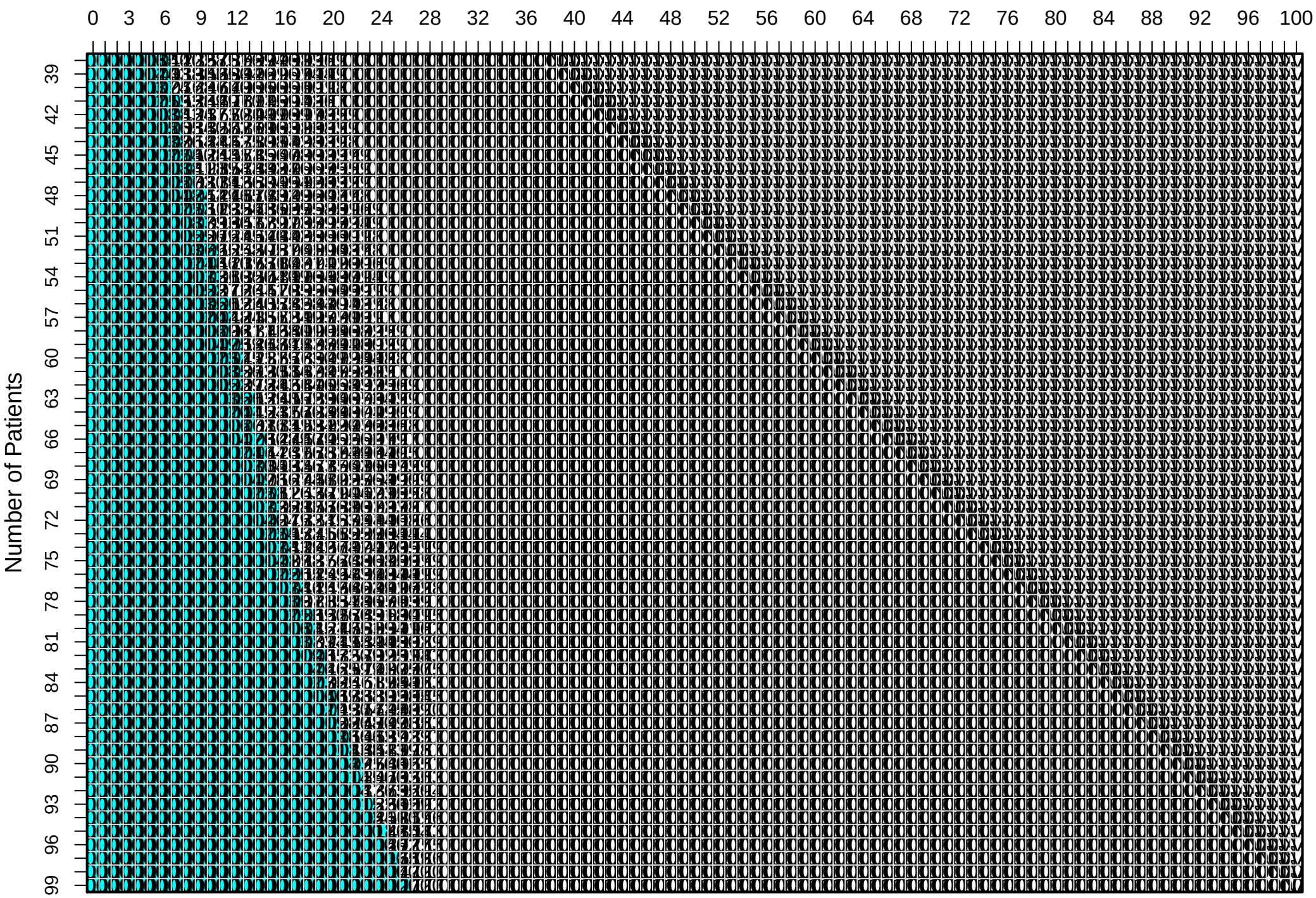

Table SB1: Futility Early Stopping Boundaries

# Patients (inclusive)	# Responses (inclusive) are considered futile	Actions
38	0 − 6	Early stopping
39	0 − 6	Early stopping
40	0 − 6	Early stopping
41	0 − 7	Early stopping
42	0 − 7	Early stopping
43	0 − 7	Early stopping
44	0 − 7	Early stopping
45	0 − 8	Early stopping
46	0 − 8	Early stopping
47	0 − 8	Early stopping
48	0 − 9	Early stopping
49	0 − 9	Early stopping
50	0 − 9	Early stopping
51	0 − 9	Early stopping
52	0 − 10	Early stopping
53	0 − 10	Early stopping
54	0 − 10	Early stopping
55	0 − 10	Early stopping
56	0 − 11	Early stopping
57	0 − 11	Early stopping
58	0 − 11	Early stopping
59	0 − 12	Early stopping
60	0 − 12	Early stopping
61	0 − 12	Early stopping
62	0 − 12	Early stopping
63	0 − 13	Early stopping

64	0 − 13	Early stopping
65	0 − 13	Early stopping
66	0 − 14	Early stopping
67	0 − 14	Early stopping
68	0 − 14	Early stopping
69	0 − 14	Early stopping
70	0 − 15	Early stopping
71	0 − 15	Early stopping
72	0 − 15	Early stopping
73	0 − 16	Early stopping
74	0 − 16	Early stopping
75	0 − 16	Early stopping
76	0 − 17	Early stopping
77	0 − 17	Early stopping
78	0 − 17	Early stopping
79	0 − 18	Early stopping
80	0 − 18	Early stopping
81	0 − 18	Early stopping
82	0 − 19	Early stopping
83	0 − 19	Early stopping
84	0 − 19	Early stopping
85	0 − 20	Early stopping
86	0 − 20	Early stopping
87	0 − 20	Early stopping
88	0 − 21	Early stopping
89	0 − 21	Early stopping
90	0 − 22	Early stopping
91	0 − 22	Early stopping

92	0 − 22	Early stopping
93	0 − 23	Early stopping
94	0 − 23	Early stopping
95	0 − 24	Early stopping
96	0 − 24	Early stopping
97	0 − 25	Early stopping
98	0 − 25	Early stopping
99	0 − 26	Early stopping

Table SB2A: Probability of Efficacy Stopping

Number of Responses

(Highlighted = Predictive Probability (PP) >= 0.99, where PP = Sum(Prob(θ > 0.2) >= 0.95 | current and future data))

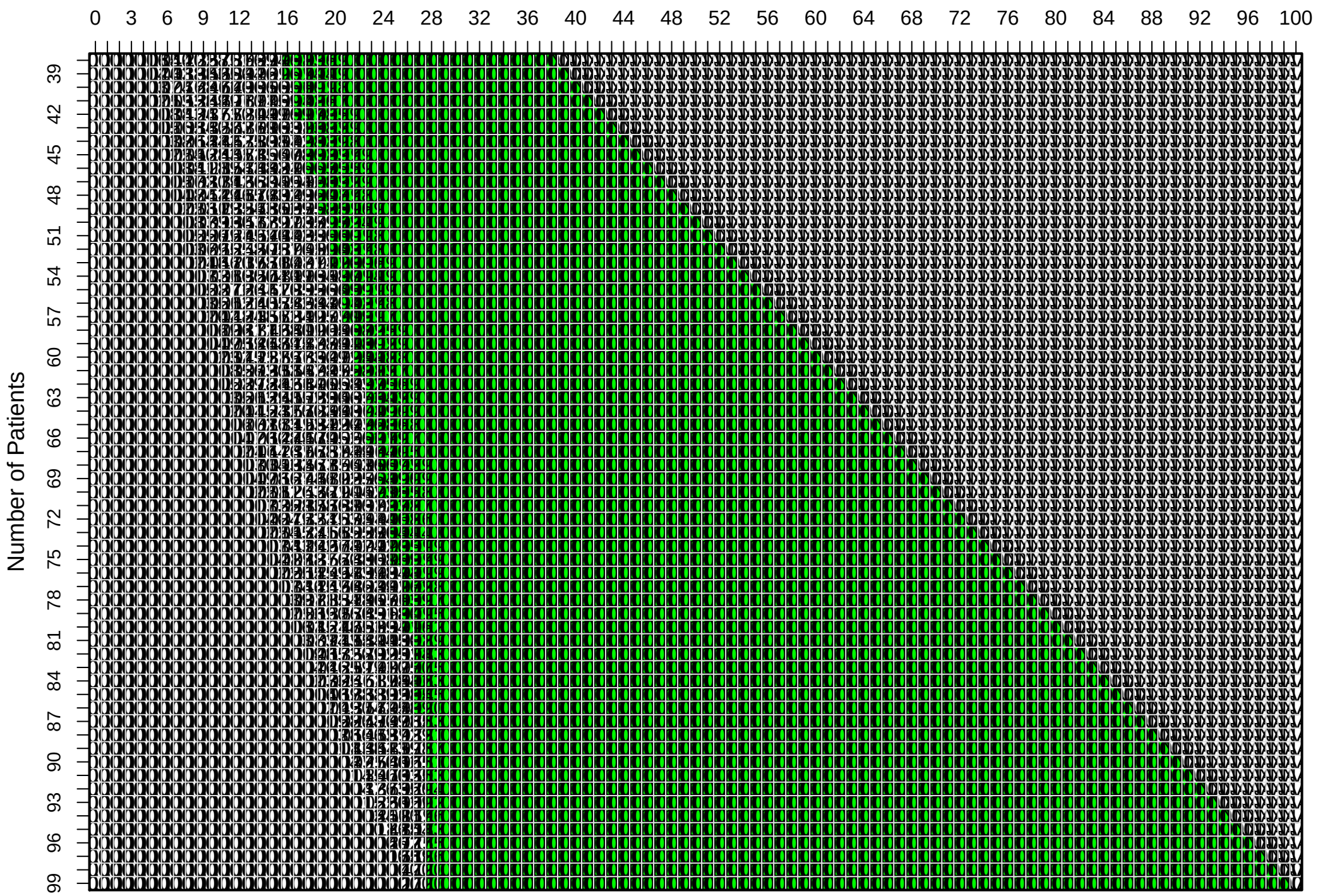

Table SB2: Efficacy Early Stopping Boundaries

# Patients (inclusive)	# Responses (inclusive) are considered efficacious	Actions
38	16 − 38	Early stopping
39	16 − 39	Early stopping
40	17 − 40	Early stopping
41	17 − 41	Early stopping
42	17 − 42	Early stopping
43	18 − 43	Early stopping
44	18 − 44	Early stopping
45	18 − 45	Early stopping
46	18 − 46	Early stopping
47	19 − 47	Early stopping
48	19 − 48	Early stopping
49	19 − 49	Early stopping
50	20 − 50	Early stopping
51	20 − 51	Early stopping
52	20 − 52	Early stopping
53	20 − 53	Early stopping
54	21 − 54	Early stopping
55	21 − 55	Early stopping
56	21 − 56	Early stopping
57	21 − 57	Early stopping
58	22 − 58	Early stopping
59	22 − 59	Early stopping
60	22 − 60	Early stopping
61	22 − 61	Early stopping
62	23 − 62	Early stopping
63	23 − 63	Early stopping

64	23 − 64	Early stopping
65	23 − 65	Early stopping
66	23 − 66	Early stopping
67	24 − 67	Early stopping
68	24 − 68	Early stopping
69	24 − 69	Early stopping
70	24 − 70	Early stopping
71	25 − 71	Early stopping
72	25 − 72	Early stopping
73	25 − 73	Early stopping
74	25 − 74	Early stopping
75	25 − 75	Early stopping
76	26 − 76	Early stopping
77	26 − 77	Early stopping
78	26 − 78	Early stopping
79	26 − 79	Early stopping
80	26 − 80	Early stopping
81	27 − 81	Early stopping
82	27 − 82	Early stopping
83	27 − 83	Early stopping
84	27 − 84	Early stopping
85	27 − 85	Early stopping
86	27 − 86	Early stopping
87	28 − 87	Early stopping
88	28 − 88	Early stopping
89	28 − 89	Early stopping
90	28 − 90	Early stopping
91	28 − 91	Early stopping

92	28 − 92	Early stopping
93	28 − 93	Early stopping
94	28 − 94	Early stopping
95	28 − 95	Early stopping
96	28 − 96	Early stopping
97	28 − 97	Early stopping
98	28 − 98	Early stopping
99	28 − 99	Early stopping

Table SB3A: Probability of Declaring Efficacy

Number of Responses

(Highlighted = Prob(θ > 0.2) >= 0.95)

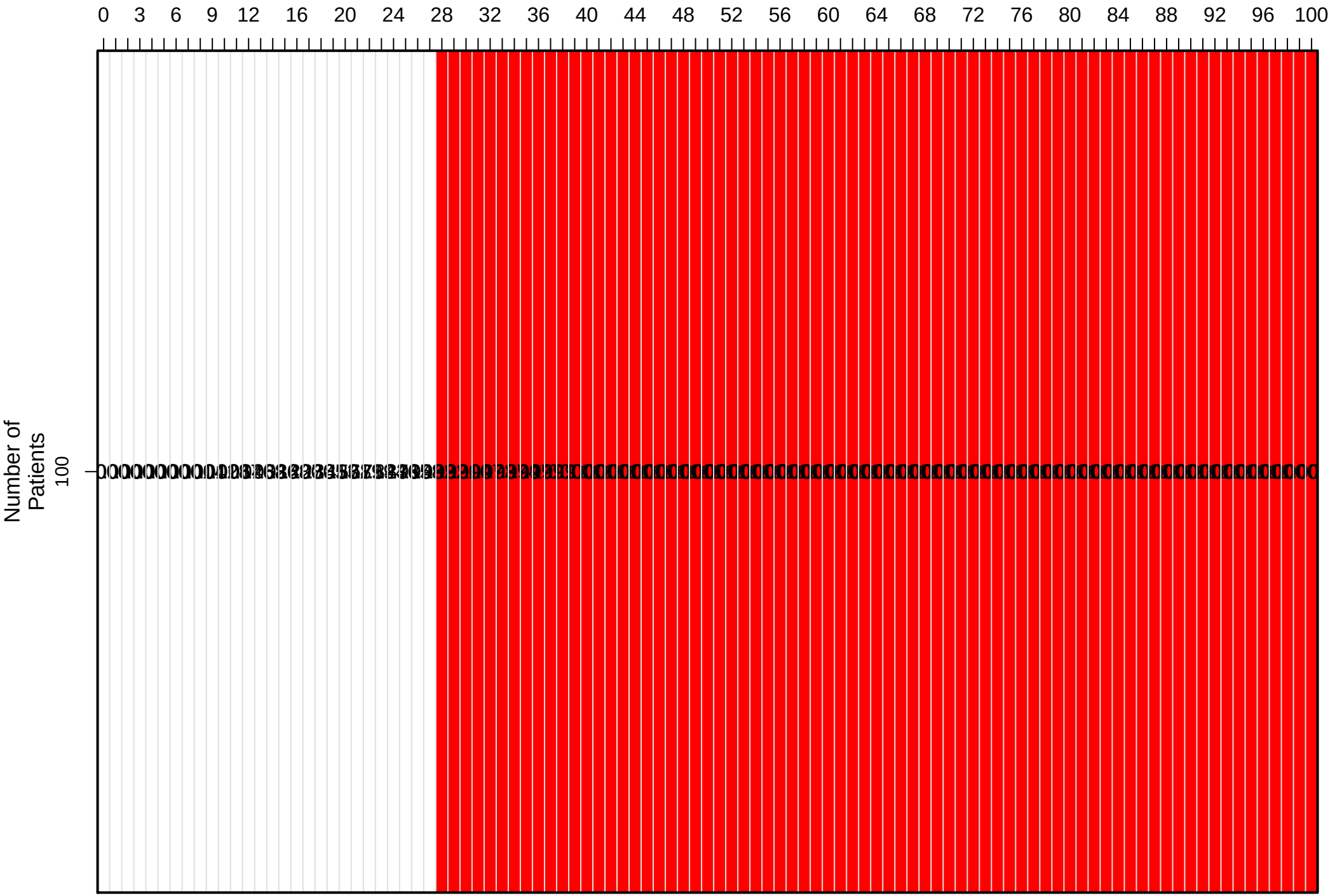

Table SB3: Stopping Boundaries for Declaring Efficacy

# Patients (inclusive)	# Responses (inclusive) are considered efficacious	Actions
100	28 − 100	Reach to Nmax