

**Supplementary Materials for "A Bayesian Phase I/II Trial Design  
for Immunotherapy"**

## Specification of admissibility probability cutoffs

In our simulation studies, we used cutoffs  $C_T = C_E = 0.05$ . To investigate the effect of higher cutoffs, we did sensitivity studies with  $C_T = C_E = 0.15$  and  $C_T = C_E = 0.3$ . Results are shown in Table S1. With higher cutoffs, the results are significantly worse for some scenarios such as scenarios 3 and 5 which had high percentages of inconclusive trials. Cutoffs  $C_T = C_E = 0.3$  yielded even worse results than cutoffs  $C_T = C_E = 0.15$ .

Table S1: Simulation results with higher cutoffs  $C_T$  and  $C_E$ .

	dose level					% inconclusive	dose level					% inconclusive
	1	2	3	4	5		1	2	3	4	5	
$C_T = C_E = 0.15$						$C_T = C_E = 0.3$						
	scenario 1											
Sel %	0.21	<b>0.68</b>	0.09	0.00	0.00	0.01	0.24	<b>0.66</b>	0.07	0.00	0.00	0.03
# patients	16.9	<b>17.1</b>	14.4	7.5	3.7		17.3	<b>17.9</b>	14.5	5.8	3.3	
	scenario 2											
Sel %	0.13	0.11	<b>0.70</b>	0.04	0.00	0.01	0.15	0.13	<b>0.63</b>	0.04	0.00	0.04
# patients	14.3	14.7	<b>15.2</b>	10.0	5.4		16.4	15.9	<b>14.9</b>	7.4	3.6	
	scenario 3											
Sel %	0.03	0.01	0.26	<b>0.49</b>	0.03	0.19	0.01	0.01	0.20	<b>0.24</b>	0.01	0.53
# patients	8.4	9.2	14.8	<b>14.4</b>	7.1		6.4	7.1	11.8	<b>10.4</b>	4.1	
	scenario 4											
Sel %	0.02	0.01	0.01	0.27	<b>0.66</b>	0.03	0.01	0.02	0.03	0.21	<b>0.53</b>	0.19
# patients	8.7	8.5	12.0	14.7	<b>15.1</b>		8.1	7.6	10.6	12.1	<b>12.3</b>	
	scenario 5											
Sel %	0.02	0.05	<b>0.40</b>	<b>0.34</b>	0.09	0.10	0.03	0.05	<b>0.36</b>	<b>0.27</b>	0.04	0.24
# patients	12.2	13.0	<b>12.0</b>	<b>10.6</b>	8.1		11.5	12.6	<b>11.9</b>	<b>8.7</b>	5.5	
	scenario 6											
Sel %	0.02	0.01	0.11	<b>0.33</b>	<b>0.51</b>	0.02	0.01	0.01	0.09	<b>0.39</b>	<b>0.43</b>	0.07
# patients	10.3	11.2	12.2	<b>12.7</b>	<b>12.7</b>		10.2	10.6	11.9	<b>12.7</b>	<b>11.4</b>	
	scenario 7											
Sel %	0.20	0.03	0.04	0.11	<b>0.63</b>	0.00	0.25	0.02	0.05	0.08	<b>0.57</b>	0.03
# patients	13.9	11.9	11.2	11.2	<b>11.7</b>		15.8	11.7	10.9	10.3	<b>10.0</b>	
	scenario 8											
Sel %	0	0	0	0	0	1	0	0	0	0	0	1
# patients	3.3	3.0	1.7	0.6	0.1		3.0	1.7	0.3	0.1	0.0	

Table S2: Simulation results with alternative prior estimates of  $\alpha$ 's in the Emax model.

	dose level					dose level				
	1	2	3	4	5	1	2	3	4	5
	$(\hat{\alpha}_0, \hat{\alpha}_1, \hat{\alpha}_2, \hat{\alpha}_3) = (2, 4, 0.4, 3)$					$(\hat{\alpha}_0, \hat{\alpha}_1, \hat{\alpha}_2, \hat{\alpha}_3) = (1.5, 6, 0.6, 2.5)$				
	scenario 1									
Selection %	0.254	<b>0.671</b>	0.073	0	0	0.271	<b>0.642</b>	0.087	0	0
# of patients	16.1	<b>16.1</b>	14.1	8.8	4.9	16.2	<b>15.8</b>	14.1	9.2	4.7
	scenario 2									
Selection %	0.121	0.106	<b>0.728</b>	0.042	0.003	0.123	0.109	<b>0.702</b>	0.062	0.002
# of patients	12.8	14.1	<b>14.5</b>	11.4	7.2	13.5	14.2	<b>14.8</b>	10.7	6.8
	scenario 3									
Selection %	0.016	0.001	0.296	<b>0.612</b>	0.043	0.03	0.007	0.276	<b>0.595</b>	0.05
# of patients	9.1	9.8	14.6	<b>16.0</b>	9.7	9.0	9.8	15.1	<b>15.5</b>	9.3
	scenario 4									
Selection %	0.001	0.001	0.006	0.262	<b>0.73</b>	0.012	0.001	0.01	0.264	<b>0.713</b>
# of patients	8.1	8.8	11.9	15.3	<b>15.9</b>	8.4	8.9	12.2	14.9	<b>15.6</b>
	scenario 5									
Selection %	0.032	0.042	<b>0.420</b>	<b>0.439</b>	0.053	0.026	0.044	<b>0.43</b>	<b>0.416</b>	0.07
# of patients	11.6	12.5	<b>13.0</b>	<b>12.3</b>	10.1	11.5	12.7	<b>13.0</b>	<b>12.3</b>	10.1
	scenario 6									
Selection %	0.002	0.009	0.091	<b>0.408</b>	<b>0.486</b>	0.005	0.01	0.1	<b>0.357</b>	<b>0.526</b>
# of patients	10.4	11.0	12.6	<b>13.1</b>	<b>12.8</b>	10.1	11.3	12.2	<b>13.1</b>	<b>13.1</b>
	scenario 7									
Selection %	0.17	0.03	0.036	0.09	<b>0.674</b>	0.178	0.01	0.036	0.07	<b>0.706</b>
# of patients	12.4	11.7	11.9	11.9	<b>12.2</b>	11.9	11.7	11.7	12.4	<b>12.2</b>
	scenario 8									
Selection %	0	0	0	0	0	0	0	0	0	0
# of patients	4.3	3.2	2.9	2.1	0.8	4.4	3.2	3.0	2.1	0.7

Table S3: Results using Gamma priors for  $\beta_1$  and  $\beta_2$ .

	dose level					dose level				
	1	2	3	4	5	1	2	3	4	5
	scenario 1					scenario 2				
Selection %	0.273	<b>0.644</b>	0.079	0.000	0.002	0.162	0.103	<b>0.708</b>	0.026	0.003
# of patients	16.2	<b>16.0</b>	14.3	8.8	4.7	13.6	14.1	<b>15.0</b>	10.9	6.3
	scenario 3					scenario 4				
Selection %	0.033	0.001	0.326	<b>0.552</b>	0.028	0.007	0.003	0.026	0.401	<b>0.521</b>
# of patients	9.9	9.7	14.7	<b>15.4</b>	8.3	9.6	8.7	12.2	13.6	<b>13.7</b>
	scenario 5					scenario 6				
Selection %	0.034	0.042	<b>0.456</b>	<b>0.408</b>	0.044	0.020	0.004	0.074	<b>0.440</b>	<b>0.460</b>
# of patients	12.3	12.3	<b>13.1</b>	<b>12.0</b>	9.8	10.6	11.1	12.4	<b>12.8</b>	<b>13.1</b>
	scenario 7					scenario 8				
Selection %	0.261	0.028	0.052	0.135	<b>0.516</b>	0.000	0.000	0.000	0.000	0.000
# of patients	13.6	12.2	11.4	11.2	<b>11.2</b>	4.7	0.4	0.0	0.0	0.0

Table S4: Results using truncated normal priors for  $\beta_1$  and  $\beta_2$ .

	dose level					dose level				
	1	2	3	4	5	1	2	3	4	5
	scenario 1					scenario 2				
Selection %	0.251	<b>0.658</b>	0.087	0.001	0.001	0.149	0.103	<b>0.718</b>	0.029	0.001
# of patients	15.9	<b>16.1</b>	14.3	8.9	4.7	13.9	14.6	<b>15.0</b>	10.6	5.9
	scenario 3					scenario 4				
Selection %	0.036	0.004	0.350	<b>0.534</b>	0.028	0.018	0.002	0.026	0.462	<b>0.462</b>
# of patients	10.3	10.5	14.8	<b>14.9</b>	7.8	11.0	9.7	11.7	13.0	<b>13.0</b>
	scenario 5					scenario 6				
Selection %	0.028	0.046	<b>0.558</b>	<b>0.340</b>	0.012	0.007	0.021	0.103	<b>0.453</b>	<b>0.414</b>
# of patients	12.5	12.8	<b>13.1</b>	<b>11.9</b>	9.2	10.6	11.4	12.6	<b>12.9</b>	<b>12.4</b>
	scenario 7					scenario 8				
Selection %	0.256	0.030	0.072	0.132	<b>0.502</b>	0.000	0.000	0.000	0.000	0.000
# of patients	14.0	12.2	11.6	10.5	<b>11.2</b>	4.9	0.3	0.0	0.0	0.0

Figure S1: Selection percentage and the average number of patients treated at each dose level under cohort sizes of 3 and 1. Each row represents a scenario. In each plot, the two bars from left to right represent cohort size of 3 and 1, respectively.

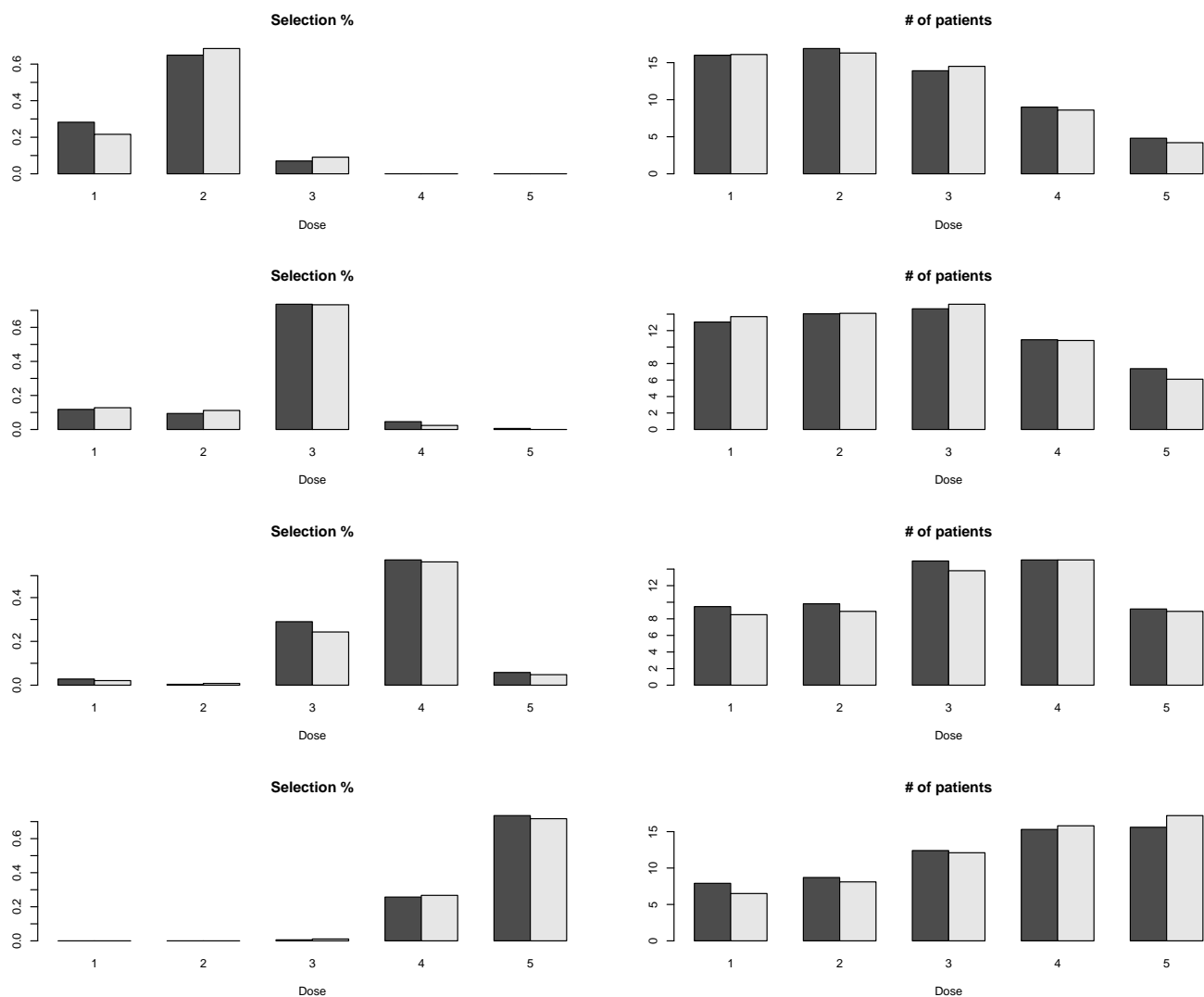


Figure S1 continued.

