

Appendix 1. Schedule of Events: Screening, Initial Dose Escalation and Build-up

Phase of trial			IDE ³		Build-up													
Week	-2 to -1		0	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28
Day	-14 to -1		0	1	14	28	42	56	70	84	98	112	126	140	154	168	182	196
Visit	-2	-1	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
GENERAL ASSESSMENTS																		
Informed Consent	x																	
Demographics	x																	
Medical History	x																	
Peanut Allergy History	x																	
Comprehensive Physical Exam	x																	
Brief Physical Exam			x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vital Signs	x		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Concomitant Medications	x	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Adverse Events	x	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
ADMINISTRATION OF STUDY MEDICATION																		
Randomization			x															
Initial Dose Escalation			x															
OIT or Placebo			x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
DISEASE-SPECIFIC ASSESSMENTS																		
Diet and Allergy Assessment	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Skin Prick Test ^{1 5}	x																	
0.5 g Oral Food Challenge ⁴		x																
5 g Oral Food Challenge ⁴																		
LOCAL LAB ASSESSMENTS																		
CBC with differential	x					x				x					x			
MECHANISTIC ASSESSMENTS																		
IgE to food allergens ¹⁵	x																	
IgE to inhalant allergens ¹⁵	x																	
Basophil Activation Assay ²	x					x				x					x			
Cellular Assays	x					x				x					x			
Plasma Assays	x					x				x					x			
Stool & Saliva Assays	x																	
HLA																		

¹ Skin Prick Test and IgE can be done up to 14 days prior to visit 0.

² Venous blood samples drawn at Stanford University will be assayed for basophil activation one day after the blood draw for comparison with samples from other sites that are shipped overnight to Stanford University.

³ IDE: Initial Dose Escalation (refer to Section 3)

⁴ Amounts expressed in peanut protein

⁵ Please see complete list of allergens in Section 6.4.1.2

Appendix 2. Schedule of Events: Maintenance and Avoidance

Phase of trial	Maintenance								Avoidance				
Week	30	43	56	69	82	95	108	121	134	136	160	162	
Day	210	301 301	392	483	574	665	756	847	938	952	1120	1134	
Visit	16	17	18	19	20	21	22	23	24	25	26	27	Unscheduled
GENERAL ASSESSMENTS													
Informed Consent													
Demographics													
Medical History													
Peanut Allergy History													
Comprehensive Physical Exam							x		x		x		
Brief Physical Exam	x	x	x	x	x	x		x		x			x
Vital Signs	x	x	x	x	x	x	x	x	x	x	x		x
Concomitant Medications	x	x	x	x	x	x	x	x	x	x	x		x
Adverse Events	x	x	x	x	x	x	x	x	x	x	x		x
ADMINISTRATION OF STUDY MEDICATION													
Randomization													
Initial Dose Escalation													
OIT or Placebo	x	x	x	x	x	x	x	x					
DISEASE-SPECIFIC ASSESSMENTS													
Diet and Allergy Assessment	x	x	x	x	x	x	x	x	x	x	x		x
Skin Prick Test ⁵	x				x				x		x		
0.5 g Oral Food Challenge ⁴													
5 g Oral Food Challenge ⁴									x		x		
LOCAL LABORATORY ASSESSMENTS													
II: CBC with differential	x		x			x			x	x	x	x	x
MECHANISTIC ASSESSMENTS													
IgE to food allergens ⁵	x				x				x		x		x
IgE to inhalant allergens ⁵					x				x				x
Basophil Activation Assay ²	x		x			x			x	x	x	x	
Cellular Assays	x		x			x			x	x	x	x	x
Plasma Assays	x		x			x			x	x	x	x	x
Saliva & Stool Assays	x				x				x		x		x ⁶
HLA ⁷						x							

¹ Skin Prick Test and IgE can be done up to 14 days prior to visit 0.

² Venous blood samples drawn at Stanford University will be assayed for basophil activation one day after the blood draw for comparison with samples from other sites that are shipped overnight to Stanford University.

⁴ Amounts expressed in peanut protein

⁵ Please see complete list of allergens in Section 6.4.1.2

⁶ Stool collection only, no saliva on Unscheduled visits

⁷ Buccal swabs