Systemic Adverse Reactions: In-Clinic Day 0–3, Solicited by Dose Number*

	Study Group																							
	Group D BioThrax 7IM (BioThrax Doses 1, 3-8) Weeks-0-4-26† Months 12-18-30-42								Placebo‡ Control SC/IM (Doses 1-8) Weeks-0-2-4-26 Months 12-18-30-42								Group A BioThrax 8SC (BioThrax Doses 1-8) Weeks-0-2-4-26 Months 12-18-30-42							
Number of Subjects (N)**	256								260								259							
	Dose								Dose								Dose							
	1	2†	3	4	5	6	7	8	1	2	3	4	5	6	7	8	1	2	3	4	5	6	7	8
Systemic Adverse Reactions	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%
Presence of any systemic adverse reaction	18	*12*	24	19	15	19	10	9	10	10	13	11	13	8	13	4	16	20	18	21	18	14	20	17
Fatigue	9	*4*	12	10	9	11	4	6	5	4	7	7	8	5	10	3	9	12	8	12	12	10	10	13
Muscle ache	8	*4*	13	6	5	5	3	5	2	2	3	4	5	3	1	1	5	8	4	5	4	3	9	5
Headache	6	*6*	9	7	8	8	5	4	4	6	5	4	7	4	6	1	7	9	8	11	7	5	9	2
Fever >100.4°F	0	*0*	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Tender/painful axillary adenopathy	0	*0*	0	1	1	1	0	0	0	0	0	0	0	0	0	1	0	1	2	1	1	0	1	0
Presence of any moderate/ severe systemic adverse reactions††	2	*2*	6	3	3	5	4	3	1	2	2	1	3	1	2	1	2	5	4	3	3	2	3	2

* Per-dose, statistical assessment performed on Intent-to-Treat population data. Evaluations performed at 15-60 minutes and 1-3 days following each injection and prior to the next scheduled injection.
** N is the highest number per treatment arm (received at least one dose); denominator (N) varied with dose number due to attrition over time.
† Subjects received saline (instead of BioThrax) for the Week 2 dose. Placebo dose data for 7IM group is in italics.
‡ The two saline groups (SC and IM) were combined.
†† Moderate = causes discomfort and interferes with normal daily activities; Severe = incapacitating and completely prevents performing normal daily activities. This is based on the systemic AE categories of fatigue, muscle ache, headache, and fever.