Local 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
Local Adverse Reactions	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%
Presence of any local adverse reaction	60	*23*	68	68	69	77	76	73	22	22	19	27	25	29	25	18	81	89	80	84	81	84	84	92
Warmth	4	*1*	8	10	11	13	14	19	1	0	0	0	0	0	1	1	29	41	32	39	34	40	51	49
Tenderness	46	*7*	51	47	41	44	44	48	6	8	7	10	6	7	7	4	64	72	48	65	53	57	61	63
Itching	1	*0*	2	4	7	7	7	10	0	0	0	0	1	0	0	0	3	16	23	20	17	22	25	26
Pain	16	*4*	20	15	16	13	16	15	4	2	3	4	4	2	3	2	16	22	12	19	16	14	18	20
Arm motion limitation	14	*1*	15	11	10	10	15	9	1	0	2	1	1	1	1	0	8	12	5	11	10	5	8	5
Erythema	15	*10*	20	30	35	48	40	37	11	12	7	13	14	17	14	11	53	64	57	65	64	64	68	71
Induration	7	*7*	12	16	21	23	15	17	1	3	2	3	4	4	3	3	26	35	28	40	38	36	38	35
Edema	5	*2*	11	20	15	23	30	25	3	4	4	4	4	7	8	5	17	33	31	33	31	35	37	46
Nodule	3	*0*	4	5	8	9	6	5	0	2	0	1	2	0	2	0	39	42	36	26	26	23	21	27
Bruise	5	*4*	5	3	2	4	3	2	4	5	1	4	3	5	5	4	6	7	6	6	3	6	5	6
Presence of any moderate/ severe local adverse reactions§	5	*1*	8	7	4	5	6	4	0	0	0	0	0	0	0	0	7	16	8	13	10	7	12	14
Presence of any large local adverse reaction¦	0	*0*	0	2	2	4	2	2	0	0	0	0	0	0	0	0	0	1	4	2	1	2	2	4

* 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 local AE categories of warmth, tenderness, itching, pain, and arm motion limitation.
¦ Large = an occurrence of induration, erythema, edema, nodule, and bruise with a largest diameter greater than 120 mm.