

Listing 16.2.7.1
Adverse Events - CRF Data only

Part A

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
A0001	Group A3	Placebo MAP	1	MAP reaction site 1,2,3 Erythema	09-MAR-2018	14:27	16-MAR-2018	11:47	Recovered / Resolved	Mild	Probably Related	None	No
A0002	Group A1	A/Sing MAP, 15 ug	1	Fatigue	10-MAR-2018	10:00	10-MAR-2018	22:00	Recovered / Resolved	Mild	Unlikely Related	None	No
A0003	Group A1	A/Sing MAP, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
A0004	Group A3	Placebo MAP	1	Intermittent Headache	13-MAR-2018	05:40	30-MAR-2018	07:40	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No
A0004	Group A3	Placebo MAP	2	MAP reaction site 1,2,3 erythema	09-MAR-2018	14:57	16-MAR-2018	15:47	Recovered / Resolved	Mild	Probably Related	None	No
A0005	Group A1	A/Sing MAP, 15 ug	18	MAP Site Reaction 1,2,3 tenderness, itchiness and oedema	12-MAR-2018	13:43	16-MAR-2018	12:42	Recovered / Resolved	Mild	Probably Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

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A0006	Group A3	Placebo MAP	10	MAP 1,2,3 visibility	08-MAY-2018	14:42	22-MAY-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
A0007	Group A1	A/Sing MAP, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
A0008	Group A3	Placebo MAP	7	MAP 2 erythema	09-MAR-2018	16:00	12-MAR-2018	16:23	Recovered / Resolved	Mild	Probably Related	None	No
A0009	Group A1	A/Sing MAP, 15 ug	1	Erythema - Left Upper Back	14-MAR-2018	16:00	24-MAR-2018	12:00	Recovered / Resolved	Mild	Possibly Related	None	No
A0009	Group A1	A/Sing MAP, 15 ug	11	MAP visibility 1,2,3	01-MAY-2018	14:51	12-JUN-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
A0010	Group A3	Placebo MAP	1	Upper Respiratory Tract Infection	26-MAR-2018	UK:UK	31-MAR-2018	UK:UK	Recovered / Resolved	Mild	Not Related	None	No

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A0011	Group A3	Placebo MAP	1	Headache	11-MAR-2018	12:45	11-MAR-2018	UK:UK	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No
A0012	Group A1	A/Sing MAP, 15 ug	1	Left ankle inversion injury	11-MAR-2018	09:00	14-APR-2018	13:15	Recovered / Resolved	Mild	Not Related	None	No
A0012	Group A1	A/Sing MAP, 15 ug	11	MAP reaction 1,3 erythema	09-MAR-2018	16:18	16-MAR-2018	15:54	Recovered / Resolved	Mild	Probably Related	None	No
A0012	Group A1	A/Sing MAP, 15 ug	12	MAP reaction 1,2 oedema	12-MAR-2018	13:50	16-MAR-2018	15:54	Recovered / Resolved	Mild	Probably Related	None	No
A0013	Group A1	A/Sing MAP, 15 ug	6	MAP 2 reaction Itchiness	16-MAR-2018	15:52	30-MAR-2018	14:40	Recovered / Resolved	Mild	Possibly Related	None	No
A0013	Group A1	A/Sing MAP, 15 ug	12	MAP 1, 2, 3 reaction Erythema	09-MAR-2018	16:23	16-MAR-2018	15:53	Recovered / Resolved	Mild	Probably Related	None	No
A0013	Group A1	A/Sing MAP, 15 ug	13	MAP 1, 2, 3 Visibility	10-MAY-2018	13:25	10-JUN-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
A0013	Group A1	A/Sing MAP, 15 ug	14	MAP 2 & 3 reaction Oedema	12-MAR-2018	13:19	16-MAR-2018	15:53	Recovered / Resolved	Mild	Probably Related	None	No

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A0014	Group A3	Placebo MAP		[No Treatment-Emergent Adverse Events Reported]									
A0015	Group A1	A/Sing MAP, 15 ug	1	Headache	11-MAR-2018	00:00	12-MAR-2018	10:30	Recovered / Resolved	Mild	Unlikely Related	None	No
A0015	Group A1	A/Sing MAP, 15 ug	3	MAP 2 and MAP 3 Erythema	09-MAR-2018	16:51	16-MAR-2018	14:03	Recovered / Resolved	Mild	Probably Related	None	No
A0015	Group A1	A/Sing MAP, 15 ug	5	MAP Sites 1,2,3 Visibility	16-MAR-2018	14:03	09-JUN-2018	10:00	Recovered / Resolved	Mild	Definitely Related	None	No
A0016	Group A3	Placebo MAP	7	Headache	10-MAR-2018	15:16	10-MAR-2018	19:00	Recovered / Resolved	Moderate	Possibly Related	Concomitant Medication	No
A0017	Group A3	Placebo MAP		[No Treatment-Emergent Adverse Events Reported]									

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A0018	Group A1	A/Sing MAP, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
A0019	Group A3	Placebo MAP	10	Phlebitis (venepuncture site)	02-APR-2018	UK:UK	14-APR-2018	UK:UK	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
A0020	Group A1	A/Sing MAP, 15 ug	1	Flu-Like Symptoms	23-MAR-2018	08:00	23-MAR-2018	11:59	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
A0021	Group A1	A/Sing MAP, 15 ug	1	Headache	10-MAR-2018	15:00	10-MAR-2018	22:00	Recovered / Resolved	Mild	Unlikely Related	None	No
A0022	Group A3	Placebo MAP	1	Pruritus site #3	26-MAR-2018	UK:UK	26-MAR-2018	UK:UK	Recovered / Resolved	Mild	Possibly Related	None	No
A0023	Group A3	Placebo MAP	1	Abdomen Bloating	10-MAR-2018	22:30	10-MAR-2018	23:30	Recovered / Resolved	Mild	Possibly Related	None	No

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Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

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A0023	Group A3	Placebo MAP	2	Intermittent Headaches	12-MAR-2018	17:00	16-MAR-2018	20:30	Recovered / Resolved	Mild	Unlikely Related	None	No
A0023	Group A3	Placebo MAP	3	Abdomen Pain (Intermittent)	10-MAR-2018	22:30	16-MAR-2018	16:10	Recovered / Resolved	Mild	Possibly Related	None	No
A0023	Group A3	Placebo MAP	4	Sore Throat	24-MAR-2018	17:00	14-APR-2018	UK:UK	Recovered / Resolved	Mild	Unlikely Related	None	No
A0023	Group A3	Placebo MAP	14	Diarrhoea	11-MAR-2018	21:30	11-MAR-2018	23:30	Recovered / Resolved	Mild	Possibly Related	None	No
A0023	Group A3	Placebo MAP	15	Drowsiness	16-MAR-2018	07:00	04-APR-2018	UK:UK	Recovered / Resolved	Mild	Unlikely Related	None	No
A0024	Group A1	A/Sing MAP, 15 ug	1	Abdominal discomfort	14-MAR-2018	14:00	15-MAR-2018	12:00	Recovered / Resolved	Mild	Unlikely Related	None	No
A0025	Group A3	Placebo MAP	1	Headache (intermittent)	15-MAR-2018	07:30	17-MAR-2018	10:00	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No
A0027	Group A3	Placebo MAP	1	Headache	16-MAR-2018	11:00	16-MAR-2018	UK:UK	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No

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A0028	Group A1	A/Sing MAP, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
A0029	Group A1	A/Sing MAP, 15 ug	6	MAP visibility site 1,2,3	09-MAY-2018	16:19	UN-Jul-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
A0030	Group A3	Placebo MAP	1	Upper Respiratory Tract Infection	30-MAR-2018	20:00	12-APR-2018	08:00	Recovered / Resolved	Mild	Not Related	None	No
A0030	Group A3	Placebo MAP	5	MAP site 1,2,3 Visibility	15-MAY-2018	12:25	30-OCT-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
A0031	Group A2	Afluria Quad IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									

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A0032	Group A4	A/Sing Mono IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
A0033	Group A2	Afluria Quad IM, 15 ug	1	Headache	17-MAR-2018	07:30	17-MAR-2018	10:00	Recovered / Resolved	Mild	Possibly Related	None	No
A0033	Group A2	Afluria Quad IM, 15 ug	2	Cough	17-MAR-2018	07:30	17-MAR-2018	10:00	Recovered / Resolved	Mild	Not Related	None	No
A0034	Group A4	A/Sing Mono IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
A0035	Group A4	A/Sing Mono IM, 15 ug	1	Tenderness at injection site	16-MAR-2018	14:15	16-MAR-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No

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A0036	Group A2	Afluria Quad IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
A0037	Group A4	A/Sing Mono IM, 15 ug	1	Injection site pain	17-MAR-2018	11:36	20-MAR-2018	08:35	Recovered / Resolved	Mild	Probably Related	None	No
A0037	Group A4	A/Sing Mono IM, 15 ug	2	Pain Left Deltoid (Injection site arm)	18-MAR-2018	15:00	25-MAR-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
A0038	Group A2	Afluria Quad IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
A0039	Group A2	Afluria Quad IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									

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A0040	Group A4	A/Sing Mono IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
A0041	Group A4	A/Sing Mono IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
A0042	Group A2	Afluria Quad IM, 15 ug	1	Upper respiratory tract infections	18-MAR-2018	07:00	21-MAR-2018	09:00	Recovered / Resolved	Mild	Not Related	None	No
A0043	Group A2	Afluria Quad IM, 15 ug	1	Right arm tenderness	19-MAR-2018	23:00	24-MAR-2018	12:20	Recovered / Resolved	Mild	Unlikely Related	None	No
A0043	Group A2	Afluria Quad IM, 15 ug	2	Right Middle Ear Infection	04-APR-2018	18:00	21-APR-2018	UK:UK	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No

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A0044	Group A4	A/Sing Mono IM, 15 ug	1	Gastroenteritis	27-MAR-2018	20:00	01-APR-2018	UK:UK	Recovered / Resolved	Mild	Unlikely Related	Concomitant Medication	No
A0045	Group A2	Afluria Quad IM, 15 ug	1	Upper respiratory tract infection	23-MAR-2018	05:30	23-MAR-2018	UK:UK	Recovered / Resolved	Mild	Not Related	None	No
A0046	Group A4	A/Sing Mono IM, 15 ug	1	Vasovagal symptoms	17-MAR-2018	12:20	17-MAR-2018	12:30	Recovered / Resolved	Mild	Not Related	None	No
A0046	Group A4	A/Sing Mono IM, 15 ug	2	Headache	21-MAR-2018	UK:UK	21-MAR-2018	UK:UK	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No
A0046	Group A4	A/Sing Mono IM, 15 ug	3	Dysmenorrhea	18-MAR-2018	UK:UK	23-MAR-2018	UK:UK	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No
A0047	Group A2	Afluria Quad IM, 15 ug	1	Headache	17-MAR-2018	17:30	18-MAR-2018	19:00	Recovered / Resolved	Moderate	Possibly Related	Concomitant Medication	No
A0047	Group A2	Afluria Quad IM, 15 ug	2	Fatigue	17-MAR-2018	17:30	18-MAR-2018	UK:UK	Recovered / Resolved	Mild	Possibly Related	None	No
A0048	Group A4	A/Sing Mono IM, 15 ug	2	Upper respiratory tract infection	18-MAR-2018	15:00	30-MAR-2018	12:00	Recovered / Resolved	Mild	Not Related	None	No

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A0048	Group A4	A/Sing Mono IM, 15 ug	3	Injection site itchiness	17-MAR-2018	23:00	18-MAR-2018	01:00	Recovered / Resolved	Mild	Definitely Related	None	No
A0049	Group A2	Afluria Quad IM, 15 ug	1	Fatigue	18-MAR-2018	08:30	20-MAR-2018	08:00	Recovered / Resolved	Mild	Possibly Related	None	No
A0049	Group A2	Afluria Quad IM, 15 ug	2	Musculoskeletal aches	18-MAR-2018	08:30	20-MAR-2018	08:00	Recovered / Resolved	Mild	Possibly Related	None	No
A0050	Group A4	A/Sing Mono IM, 15 ug	[No Treatment-Emergent Adverse Events Reported]										
A0051	Group A2	Afluria Quad IM, 15 ug	[No Treatment-Emergent Adverse Events Reported]										

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A0052	Group A4	A/Sing Mono IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
A0053	Group A4	A/Sing Mono IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
A0054	Group A2	Afluria Quad IM, 15 ug	1	Shortness of Breath	20-MAR-2018	15:30	20-MAR-2018	16:30	Recovered / Resolved	Mild	Unlikely Related	Other Safety Bloods, ECG, Vital Signs + Oxygen Saturation	No
A0055	Group A4	A/Sing Mono IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									

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A0056	Group A2	Afluria Quad IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
A0057	Group A4	A/Sing Mono IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
A0058	Group A2	Afluria Quad IM, 15 ug	1	Upper Respiratory Tract Infection	11-MAY-2018	08:00	19-MAY-2018	UK:UK	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
A0059	Group A2	Afluria Quad IM, 15 ug	1	Intermittent Headache	28-MAR-2018	16:30	27-APR-2018	21:00	Recovered / Resolved	Mild	Unlikely Related	Concomitant Medication	No
A0060	Group A4	A/Sing Mono IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part A

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
A1026	Group A1	A/Sing MAP, 15 ug		[No Treatment-Emergent Adverse Events Reported]									

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0001	Group B1	A/Sing MAP, 15 ug	1	MAP Erythema sites 1, 2 and 3	10-MAY-2018	09:06	UN-Jun-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0002	Group B2	Placebo MAP	1	Adhesive tapes irritation	07-MAY-2018	11:00	11-MAY-2018	13:17	Recovered / Resolved	Mild	Not Related	None	No
B0003	Group B2	Placebo MAP	1	Biopsy site -1 inflamed scar	28-MAY-2018	UK:UK	UN-Jun-2018	UK:UK	Recovered / Resolved	Mild	Unlikely Related	None	No
B0004	Group B1	A/Sing MAP, 15 ug	1	Erythema MAP sites 1, 2 & 3	10-MAY-2018	14:49	11-JUN-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0005	Group B1	A/Sing MAP, 15 ug	1	MAP reaction site 1,2,3 Erythema	10-MAY-2018	09:34	06-JUL-2018	17:10	Recovered / Resolved	Mild	Definitely Related	None	No
B0005	Group B1	A/Sing MAP, 15 ug	3	Sore throat	11-MAY-2018	00:00	28-MAY-2018	13:55	Recovered / Resolved	Mild	Unlikely Related	None	No
B0005	Group B1	A/Sing MAP, 15 ug	4	Skin Dysesthesia	20-MAY-2018	18:00	11-JUN-2018	UK:UK	Recovered / Resolved	Mild	Unlikely Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0006	Group B2	Placebo MAP	1	Biopsy site pain	07-MAY-2018	12:30	11-JUN-2018	UK:UK	Recovered / Resolved	Mild	Not Related	None	No
B0007	Group B2	Placebo MAP	1	Headache	09-MAY-2018	16:00	17-MAY-2018	14:00	Recovered / Resolved	Mild	Possibly Related	Concomitant Medication	No
B0008	Group B1	A/Sing MAP, 15 ug	1	Nasal congestion	08-MAY-2018	09:00	09-MAY-2018	22:30	Recovered / Resolved	Mild	Possibly Related	None	No
B0008	Group B1	A/Sing MAP, 15 ug	2	MAP 1,2,3 Erythema	10-MAY-2018	09:13	UN-Jun-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0009	Group B1	A/Sing MAP, 15 ug	1	MAP site 2,3 reaction erythema	10-MAY-2018	09:56	11-JUN-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0010	Group B2	Placebo MAP	1	Pain on biopsy site - Right arm	07-MAY-2018	16:00	12-MAY-2018	23:00	Recovered / Resolved	Mild	Not Related	Concomitant Medication	No
B0010	Group B2	Placebo MAP	2	Sore throat	12-MAY-2018	07:00	15-MAY-2018	UK:UK	Recovered / Resolved	Mild	Possibly Related	Concomitant Medication	No
B0010	Group B2	Placebo MAP	4	Parasthesia	07-MAY-2018	11:25	06-JUN-2018	11:15	Recovered / Resolved	Mild	Not Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0010	Group B2	Placebo MAP	6	Left Arm Biopsy site pain	08-MAY-2018	UK:UK	11-JUN-2018	UK:UK	Recovered / Resolved	Mild	Unlikely Related	None	No
B0011	Group B8	A/Sing MAP, 15 ug	1	MAP Reaction - Erythema sites 1,2,3	13-MAY-2018	11:01	14-JUL-2018	09:44	Recovered / Resolved	Mild	Definitely Related	None	No
B0011	Group B8	A/Sing MAP, 15 ug	2	MAP site #1 flaking	15-MAY-2018	11:15	14-JUL-2018	09:40	Recovered / Resolved	Mild	Definitely Related	None	No
B0012	Group B6	A/Sing MAP, 2.5 ug	3	MAP 1 Oedema	12-MAY-2018	12:16	19-MAY-2018	13:22	Recovered / Resolved	Mild	Probably Related	None	No
B0012	Group B6	A/Sing MAP, 2.5 ug	4	MAP 1 Erythema	13-MAY-2018	11:29	19-MAY-2018	13:22	Recovered / Resolved	Mild	Probably Related	None	No
B0013	Group B5	A/Sing MAP, 5 ug	1	Upper Respiratory Tract Infection	18-MAY-2018	08:00	11-JUL-2018	08:00	Recovered / Resolved	Mild	Not Related	Concomitant Medication	No
B0013	Group B5	A/Sing MAP, 5 ug	2	Headache	18-MAY-2018	08:00	18-MAY-2018	13:00	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No
B0013	Group B5	A/Sing MAP, 5 ug	3	Hot Flushes	12-MAY-2018	14:30	13-MAY-2018	15:00	Recovered / Resolved	Mild	Possibly Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0014	Group B3	A/Sing MAP, 15 ug	1	MAP sites 1,2,3 - Visibility	02-JUN-2018	09:33	27-AUG-2018	15:00	Recovered / Resolved	Mild	Definitely Related	None	No
B0015	Group B9	A/Sing IM, 15 ug	1	Upper Respiratory Tract Infection	15-MAY-2018	11:47	20-MAY-2018	09:00	Recovered / Resolved	Mild	Not Related	None	No
B0015	Group B9	A/Sing IM, 15 ug	2	Shingles rash Left torso	18-MAY-2018	18:00	30-JUN-2018	18:00	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No
B0016	Group B4	A/Sing MAP, 10 ug	3	Headache	26-MAY-2018	UK:UK	26-MAY-2018	UK:UK	Recovered / Resolved	Mild	Not Related	Concomitant Medication	No
B0016	Group B4	A/Sing MAP, 10 ug	4	Cervical lymphadenopathy	29-MAY-2018	23:00	25-JUL-2018	UK:UK	Recovered / Resolved	Moderate	Possibly Related	Concomitant Medication	No
B0016	Group B4	A/Sing MAP, 10 ug	7	MAP reaction - erythema + oedema site 3	15-MAY-2018	08:49	02-JUN-2018	13:05	Recovered / Resolved	Mild	Definitely Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0017	Group B7	Placebo MAP		[No Treatment-Emergent Adverse Events Reported]									
B0018	Group B9	A/Sing IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
B0020	Group B6	A/Sing MAP, 2.5 ug		[No Treatment-Emergent Adverse Events Reported]									
B0021	Group B7	Placebo MAP		[No Treatment-Emergent Adverse Events Reported]									

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0022	Group B4	A/Sing MAP, 10 ug	1	Tachycardia	12-MAY-2018	15:33	19-MAY-2018	13:12	Recovered / Resolved	Mild	Unlikely Related	None	No
B0022	Group B4	A/Sing MAP, 10 ug	2	Headache	16-MAY-2018	09:45	16-MAY-2018	11:15	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No
B0022	Group B4	A/Sing MAP, 10 ug	3	MAP visibility sites 1,2,3	12-JUL-2018	11:03	31-AUG-2018	22:29	Recovered / Resolved	Mild	Definitely Related	None	No
B0023	Group B3	A/Sing MAP, 15 ug	1	Dizziness	12-MAY-2018	13:25	12-MAY-2018	13:29	Recovered / Resolved	Mild	Unlikely Related	Other Dose - 2 delayed laid supine for a few minutes, two additional vital sign assessments conducted	No
B0023	Group B3	A/Sing MAP, 15 ug	3	MAP reaction sites 1,2&3 - oedema and erythema	12-MAY-2018	15:39	19-MAY-2018	10:22	Recovered / Resolved	Mild	Definitely Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0024	Group B5	A/Sing MAP, 5 ug	1	MAP reaction sites 1,2,3 Erythema, site 3 oedema	12-MAY-2018	14:59	19-MAY-2018	13:25	Recovered / Resolved	Mild	Definitely Related	None	No
B0024	Group B5	A/Sing MAP, 5 ug	4	Map site #3 visibility	12-JUL-2018	14:28	28-AUG-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
B0025	Group B8	A/Sing MAP, 15 ug	1	Rhinorrhea	13-MAY-2018	UK:UK	16-MAY-2018	07:00	Recovered / Resolved	Mild	Possibly Related	None	No
B0025	Group B8	A/Sing MAP, 15 ug	2	MAP site visibility 1,2,3	13-JUL-2018	13:38	21-AUG-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
B0026	Group B9	A/Sing IM, 15 ug	1	Headache	31-MAY-2018	20:00	31-MAY-2018	22:00	Recovered / Resolved	Mild	Unlikely Related	None	No
B0027	Group B3	A/Sing MAP, 15 ug	1	MAP sites 1,2,3 - oedema	12-MAY-2018	16:40	02-JUN-2018	16:08	Recovered / Resolved	Mild	Definitely Related	None	No
B0027	Group B3	A/Sing MAP, 15 ug	2	Upper Respiratory Tract Infection	25-MAY-2018	UK:UK	27-MAY-2018	UK:UK	Recovered / Resolved	Mild	Not Related	None	No
B0027	Group B3	A/Sing MAP, 15 ug	3	MAP site 3 Erythema	15-MAY-2018	17:12	22-JUN-2018	16:08	Recovered / Resolved	Mild	Probably Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0027	Group B3	A/Sing MAP, 15 ug	4	MAP Visibility sites 1 and 3	11-JUL-2018	17:20	27-AUG-2018	17:20	Recovered / Resolved	Mild	Definitely Related	None	No
B0028	Group B5	A/Sing MAP, 5 ug	1	Headache	12-MAY-2018	21:00	13-MAY-2018	UK:UK	Recovered / Resolved	Mild	Unlikely Related	None	No
B0028	Group B5	A/Sing MAP, 5 ug	3	MAP site 1 - Erythema	16-MAY-2018	16:38	02-JUN-2018	14:50	Recovered / Resolved	Mild	Definitely Related	None	No
B0029	Group B6	A/Sing MAP, 2.5 ug	2	MAP reaction site 3 erythema and oedema	13-MAY-2018	14:56	19-MAY-2018	14:23	Recovered / Resolved	Mild	Definitely Related	None	No
B0029	Group B6	A/Sing MAP, 2.5 ug	3	Upper Respiratory Tract Infection	29-MAY-2018	14:51	04-JUN-2018	09:00	Recovered / Resolved	Moderate	Not Related	None	No
B0029	Group B6	A/Sing MAP, 2.5 ug	5	MAP site 1,2,3 visibility	11-JUL-2018	14:53	04-OCT-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0030	Group B7	Placebo MAP	[No Treatment-Emergent Adverse Events Reported]										

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0031	Group B4	A/Sing MAP, 10 ug	5	MAP site 2 & 3 Reaction Erythema and induration	20-MAY-2018	13:19	26-MAY-2018	13:08	Recovered / Resolved	Mild	Definitely Related	None	No
B0032	Group B6	A/Sing MAP, 2.5 ug	1	MAP reaction site 3 erythema	22-MAY-2018	08:15	26-MAY-2018	09:08	Recovered / Resolved	Mild	Probably Related	None	No
B0032	Group B6	A/Sing MAP, 2.5 ug	2	Common cold	25-MAY-2018	20:00	28-MAY-2018	08:00	Recovered / Resolved	Mild	Unlikely Related	None	No
B0033	Group B5	A/Sing MAP, 5 ug	1	MAP reaction site 3 - erythema	20-MAY-2018	11:48	09-JUN-2018	14:00	Recovered / Resolved	Mild	Definitely Related	None	No
B0033	Group B5	A/Sing MAP, 5 ug	2	MAP site 3 visibility	18-JUL-2018	13:40	29-AUG-2018	17:53	Recovered / Resolved	Mild	Probably Related	None	No
B0034	Group B8	A/Sing MAP, 15 ug	2	Patch site reaction - Oedema + Erythema site #1	20-MAY-2018	14:05	20-JUN-2018	11:33	Recovered / Resolved	Mild	Definitely Related	None	No
B0035	Group B9	A/Sing IM, 15 ug	1	Upper Respiratory Tract Infection	31-MAY-2018	12:00	09-JUN-2018	08:00	Recovered / Resolved	Mild	Not Related	Concomitant Medication	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0036	Group	Placebo MAP B7	1	Nausea	19-MAY-2018	UK:UK	19-MAY-2018	13:00	Recovered / Resolved	Mild	Unlikely Related	None	No
B0037	Group	A/Sing MAP, B4 10 ug	1	Patch sites reaction 2,3 - erythema site	20-MAY-2018	12:02	09-JUN-2018	14:04	Recovered / Resolved	Mild	Definitely Related	None	No
B0037	Group	A/Sing MAP, B4 10 ug	3	Upper Respiratory Tract Infection	20-MAY-2018	08:30	21-MAY-2018	19:30	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
B0037	Group	A/Sing MAP, B4 10 ug	4	MAP 2 Erythema extent	22-MAY-2018	12:11	26-MAY-2018	10:55	Recovered / Resolved	Mild	Probably Related	None	No
B0037	Group	A/Sing MAP, B4 10 ug	5	MAP visibility sites 2,3	26-MAY-2018	10:56			Not recovered / Not resolved	Mild	Probably Related	None	No
B0038	Group	A/Sing MAP, B3 15 ug	1	MAP reaction site 1,2,3 erythema	20-MAY-2018	08:24	07-JUL-2018	15:50	Recovered / Resolved	Mild	Definitely Related	None	No
B0038	Group	A/Sing MAP, B3 15 ug	2	Lethargy	21-MAY-2018	12:00	27-MAY-2018	12:00	Recovered / Resolved	Mild	Possibly Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0039	Group B7	Placebo MAP	2	Headache	24-MAY-2018	21:00	25-MAY-2018	12:00	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No
B0040	Group B9	A/Sing IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
B0041	Group B3	A/Sing MAP, 15 ug	1	Musculoskeletal pain Left shoulder	20-MAY-2018	11:00	20-MAY-2018	19:00	Recovered / Resolved	Mild	Unlikely Related	None	No
B0041	Group B3	A/Sing MAP, 15 ug	2	MAP sites 1,2,3 - erythema	20-MAY-2018	13:37	26-MAY-2018	12:36	Recovered / Resolved	Mild	Definitely Related	None	No
B0041	Group B3	A/Sing MAP, 15 ug	3	MAP 1,2,3 visible	20-JUL-2018	15:24			Not recovered / Not resolved	Mild	Definitely Related	None	No
B0042	Group B5	A/Sing MAP, 5 ug	1	Patch site - 3 reaction - Erythema	20-MAY-2018	12:20	07-JUL-2018	18:16	Recovered / Resolved	Mild	Definitely Related	None	No
B0042	Group B5	A/Sing MAP, 5 ug	3	Headache	23-MAY-2018	06:15	09-JUN-2018	UK:UK	Recovered / Resolved	Moderate	Possibly Related	Concomitant Medication	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0042	Group B5	A/Sing MAP, 5 ug	5	MAP 3 Visibility	18-JUL-2018	09:30	05-SEP-2018	09:00	Recovered / Resolved	Mild	Definitely Related	None	No
B0043	Group B8	A/Sing MAP, 15 ug	1	Headache	19-MAY-2018	18:00	19-MAY-2018	19:30	Recovered / Resolved	Mild	Possibly Related	Concomitant Medication	No
B0043	Group B8	A/Sing MAP, 15 ug	2	Left arm bruise	02-JUN-2018	UK:UK	13-JUN-2018	UK:UK	Recovered / Resolved	Mild	Unlikely Related	None	No
B0043	Group B8	A/Sing MAP, 15 ug	3	Myalgia Left deltoid	02-JUN-2018	UK:UK	13-JUN-2018	UK:UK	Recovered / Resolved	Mild	Unlikely Related	None	No
B0043	Group B8	A/Sing MAP, 15 ug	4	MAP Visibility 1,2,3	18-JUL-2018	09:25			Not recovered / Not resolved	Mild	Definitely Related	None	No
B0044	Group B6	A/Sing MAP, 2.5 ug	1	MAP site 3 reaction - erythema and oedema	20-MAY-2018	12:33	07-JUL-2018	18:32	Recovered / Resolved	Mild	Definitely Related	None	No
B0044	Group B6	A/Sing MAP, 2.5 ug	3	MAP #3 visible	18-JUL-2018	13:19			Not recovered / Not resolved	Mild	Definitely Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0045	Group B4	A/Sing MAP, 10 ug	2	MAP site #2 reaction oedema and erythema	20-MAY-2018	12:37	22-MAY-2018	10:41	Recovered / Resolved	Mild	Probably Related	None	No
B0045	Group B4	A/Sing MAP, 10 ug	6	MAP site 1,2 visibility	18-JUL-2018	11:51	20-AUG-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0046	Group B7	Placebo MAP	1	Headache	24-MAY-2018	22:14	25-MAY-2018	00:10	Recovered / Resolved	Mild	Unlikely Related	Concomitant Medication	No
B0047	Group B9	A/Sing IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
B0048	Group B6	A/Sing MAP, 2.5 ug	1	MAP reaction site 1 erythema	20-MAY-2018	13:21	26-MAY-2018	10:22	Recovered / Resolved	Mild	Definitely Related	None	No
B0048	Group B6	A/Sing MAP, 2.5 ug	4	MAP visibility site 1	18-JUL-2018	15:55	01-SEP-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0049	Group B4	A/Sing MAP, 10 ug	1	MAP reaction 2,3 erythema and oedema	20-MAY-2018	14:02	22-MAY-2018	15:10	Recovered / Resolved	Mild	Definitely Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0049	Group B4	A/Sing MAP, 10 ug	4	MAP Visibility 1,2,3	18-JUL-2018	10:49			Not recovered / Not resolved	Mild	Definitely Related	None	No
B0050	Group B8	A/Sing MAP, 15 ug	1	MAP Reaction 1,2,3 - Erythema	20-MAY-2018	14:45	18-JUL-2018	14:23	Recovered / Resolved	Mild	Probably Related	None	No
B0051	Group B3	A/Sing MAP, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
B0052	Group B5	A/Sing MAP, 5 ug	1	MAP reaction - Site #1 Erythema, oedema and tenderness	26-MAY-2018	UK:UK	01-JUN-2018	13:55	Recovered / Resolved	Mild	Definitely Related	None	No
B0052	Group B5	A/Sing MAP, 5 ug	2	Left Axilla lymphadenopathy	27-MAY-2018	08:00	28-MAY-2018	07:00	Recovered / Resolved	Mild	Possibly Related	None	No
B0052	Group B5	A/Sing MAP, 5 ug	3	Upper Respiratory Tract Infection	09-JUN-2018	09:00	20-JUN-2018	08:00	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0052	Group B5	A/Sing MAP, 5 ug	4	Headache	01-JUN-2018	23:45	02-JUN-2018	06:00	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
B0052	Group B5	A/Sing MAP, 5 ug	5	Patch site 1,2,3 visibility	20-JUL-2018	14:10	18-SEP-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0053	Group B6	A/Sing MAP, 2.5 ug	1	MAP site 1,2,3 Visibility	25-JUL-2018	12:49	28-AUG-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0054	Group B5	A/Sing MAP, 5 ug	1	Upper Respiratory Tract Infection	26-MAY-2018	06:12	27-MAY-2018	10:41	Recovered / Resolved	Mild	Not Related	None	No
B0054	Group B5	A/Sing MAP, 5 ug	2	Vasovagal dizziness	15-JUN-2018	08:49	15-JUN-2018	09:04	Recovered / Resolved	Mild	Not Related	Other Trendelenburg position, Apple juice 250ml	No
B0055	Group B8	A/Sing MAP, 15 ug	1	Headache	25-MAY-2018	14:15	25-MAY-2018	16:15	Recovered / Resolved	Mild	Possibly Related	None	No
B0055	Group B8	A/Sing MAP, 15 ug	2	Upper Respiratory Tract Infection	27-MAY-2018	10:00	29-MAY-2018	10:00	Recovered / Resolved	Mild	Not Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0055	Group B8	A/Sing MAP, 15 ug	3	Tonsillitis	14-JUN-2018	14:00	17-JUN-2018	12:00	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No
B0056	Group B3	A/Sing MAP, 15 ug	2	MAP site reaction - Erythema 1,2	26-MAY-2018	UK:UK	30-MAY-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
B0056	Group B3	A/Sing MAP, 15 ug	3	MAP 1,2,3 Visibility	01-JUN-2018	08:50	28-AUG-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
B0057	Group B4	A/Sing MAP, 10 ug	1	MAP 1,2,3 Visibiity	24-JUL-2018	09:43			Not recovered / Not resolved	Mild	Probably Related	None	No
B0058	Group B9	A/Sing IM, 15 ug	1	Exacerbations of Migraine	06-JUN-2018	13:00	07-JUN-2018	08:00	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No
B0058	Group B9	A/Sing IM, 15 ug	2	Left arm (IP arm) discomfort	25-MAY-2018	13:00	25-MAY-2018	13:46	Recovered / Resolved	Mild	Probably Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0059	Group B7	Placebo MAP		[No Treatment-Emergent Adverse Events Reported]									
B0060	Group B3	A/Sing MAP, 15 ug	5	Bruise to Right elbow	25-MAY-2018	22:00	28-MAY-2018	00:45	Recovered / Resolved	Mild	Unlikely Related	None	No
B0060	Group B3	A/Sing MAP, 15 ug	6	Patch site 1 reaction erythema and oedema	28-MAY-2018	14:39	24-JUL-2018	13:52	Recovered / Resolved	Mild	Definitely Related	None	No
B0061	Group B8	A/Sing MAP, 15 ug	2	MAP sites 1,2 - Erythema	28-MAY-2018	13:37	15-JUN-2018	12:10	Recovered / Resolved	Mild	Definitely Related	None	No
B0062	Group B5	A/Sing MAP, 5 ug		[No Treatment-Emergent Adverse Events Reported]									

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0063	Group B7	Placebo MAP		[No Treatment-Emergent Adverse Events Reported]									
B0064	Group B9	A/Sing IM, 15 ug	1	Upper Respiratory Tract Infection	01-JUN-2018	16:30	20-JUN-2018	12:00	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
B0065	Group B4	A/Sing MAP, 10 ug	1	Tension Headache	25-MAY-2018	18:00	26-MAY-2018	12:26	Recovered / Resolved	Mild	Possibly Related	None	No
B0065	Group B4	A/Sing MAP, 10 ug	2	Upper Respiratory Tract Infection	08-JUN-2018	08:00	22-JUN-2018	09:00	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
B0065	Group B4	A/Sing MAP, 10 ug	3	MAP site 1 & 3 erythema	26-MAY-2018	UK:UK	15-JUN-2018	09:59	Recovered / Resolved	Mild	Probably Related	None	No
B0065	Group B4	A/Sing MAP, 10 ug	4	MAP visibility site 1,2,3	24-JUL-2018	13:54	09-OCT-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0066	Group B6	A/Sing MAP, 2.5 ug		[No Treatment-Emergent Adverse Events Reported]									
B0067	Group B8	A/Sing MAP, 15 ug	1	Itchness - MAP 1,2,3	28-MAY-2018	07:00	31-MAY-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0068	Group B5	A/Sing MAP, 5 ug	1	MAP site 2 Visibility	24-JUL-2018	17:00	10-SEP-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0068	Group B5	A/Sing MAP, 5 ug	2	MAP 2 Erythema	01-JUN-2018	09:58	16-JUN-2018	08:13	Recovered / Resolved	Mild	Probably Related	None	No
B0069	Group B7	Placebo MAP	2	Headache	06-JUN-2018	19:00	06-JUN-2018	22:00	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
B0070	Group B9	A/Sing IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0071	Group B4	A/Sing MAP, 10 ug	1	MAP reaction site 3 - Erythema	02-JUN-2018	12:33	22-JUN-2018	13:31	Recovered / Resolved	Mild	Definitely Related	None	No
B0072	Group B3	A/Sing MAP, 15 ug	1	Headache	01-JUN-2018	12:40	02-JUN-2018	11:50	Recovered / Resolved	Mild	Possibly Related	None	No
B0072	Group B3	A/Sing MAP, 15 ug	2	MAP reaction sites 1,2,3 - Erythema	02-JUN-2018	12:36	08-JUN-2018	13:46	Recovered / Resolved	Mild	Definitely Related	None	No
B0073	Group B6	A/Sing MAP, 2.5 ug	1	MAP site reaction 2 - Oedema	01-JUN-2018	13:50	08-JUN-2018	12:34	Recovered / Resolved	Mild	Definitely Related	None	No
B0073	Group B6	A/Sing MAP, 2.5 ug	2	MAP reaction sites 1,2,3 - Erythema	02-JUN-2018	12:42	06-JUN-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0074	Group B9	A/Sing IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0075	Group B3	A/Sing MAP, 15 ug	1	Sore Throat	02-JUN-2018	19:00	03-JUN-2018	10:00	Recovered / Resolved	Mild	Possibly Related	None	No
B0075	Group B3	A/Sing MAP, 15 ug	2	Headache	05-JUN-2018	08:00	05-JUN-2018	12:00	Recovered / Resolved	Mild	Not Related	Concomitant Medication	No
B0075	Group B3	A/Sing MAP, 15 ug	3	MAP 2,3 Visibility	31-JUL-2018	08:27	28-AUG-2018	10:38	Recovered / Resolved	Mild	Probably Related	None	No
B0077	Group B4	A/Sing MAP, 10 ug	1	MAP reaction site 1,3 oedema and erythema	04-JUN-2018	08:45	08-JUN-2018	19:15	Recovered / Resolved	Mild	Definitely Related	None	No
B0078	Group B8	A/Sing MAP, 15 ug	1	MAP 1,2,3 reaction - Erythema	02-JUN-2018	10:22	22-JUN-2018	12:13	Recovered / Resolved	Mild	Definitely Related	None	No
B0078	Group B8	A/Sing MAP, 15 ug	3	MAP reaction - Oedema sites 1,2,3 and site 1 itchiness	04-JUN-2018	11:32	08-JUN-2018	11:00	Recovered / Resolved	Mild	Definitely Related	None	No
B0078	Group B8	A/Sing MAP, 15 ug	4	MAP site 1,2,3 Visibility	06-AUG-2018	10:59	29-OCT-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0079	Group B6	A/Sing MAP, 2.5 ug	1	Rash- Erythema multiforme	02-JUN-2018	09:00	03-JUN-2018	10:00	Recovered / Resolved	Mild	Possibly Related	None	No
B0079	Group B6	A/Sing MAP, 2.5 ug	2	MAP site 2 - redness extension	02-JUN-2018	11:16	22-JUN-2018	12:00	Recovered / Resolved	Mild	Definitely Related	None	No
B0079	Group B6	A/Sing MAP, 2.5 ug	3	Headache	03-JUN-2018	15:00	03-JUN-2018	16:30	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No
B0079	Group B6	A/Sing MAP, 2.5 ug	4	MAP sites 2,3 -Oedema	01-JUN-2018	14:43	22-JUN-2018	12:02	Recovered / Resolved	Mild	Definitely Related	None	No
B0079	Group B6	A/Sing MAP, 2.5 ug	5	MAP 2 visibility	31-JUL-2018	12:19	22-OCT-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
B0081	Group B6	A/Sing MAP, 2.5 ug	1	MAP reaction sites 1,2,3 - Erythema and Oedema	01-JUN-2018	14:53	04-JUN-2018	14:21	Recovered / Resolved	Mild	Definitely Related	None	No
B0081	Group B6	A/Sing MAP, 2.5 ug	3	Headache	01-JUN-2018	16:45	01-JUN-2018	17:15	Recovered / Resolved	Moderate	Possibly Related	Concomitant Medication	No
B0081	Group B6	A/Sing MAP, 2.5 ug	4	Headache	08-JUN-2018	11:30	08-JUN-2018	14:30	Recovered / Resolved	Mild	Unlikely Related	Concomitant Medication	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0082	Group B3	A/Sing MAP, 15 ug	1	MAP reaction sites 1,2,3 reaction - Erythema & Oedema	02-JUN-2018	11:47	22-JUN-2018	13:47	Recovered / Resolved	Mild	Definitely Related	None	No
B0082	Group B3	A/Sing MAP, 15 ug	3	Chest pain	08-JUN-2018	05:40	08-JUN-2018	15:04	Recovered / Resolved	Moderate	Not Related	Other Unscheduled bloods and vital signs	No
B0082	Group B3	A/Sing MAP, 15 ug	4	MAP site 1,2,3 reaction - visibility	31-JUL-2018	15:19	10-SEP-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
B0083	Group B8	A/Sing MAP, 15 ug	1	MAP reaction sites 2,3 -Oedema	01-JUN-2018	15:40	08-JUN-2018	14:03	Recovered / Resolved	Mild	Definitely Related	None	No
B0083	Group B8	A/Sing MAP, 15 ug	3	MAP sites 1,2,3 reaction - Erythema	02-JUN-2018	10:00	08-JUN-2018	14:03	Recovered / Resolved	Mild	Definitely Related	None	No
B0083	Group B8	A/Sing MAP, 15 ug	4	MAP site 1,2,3 Visibility	31-JUL-2018	08:33			Not recovered / Not resolved	Mild	Probably Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0084	Group B5	A/Sing MAP, 5 ug	1	MAP 3 reaction erythema	10-JUN-2018	12:07	30-JUN-2018	14:22	Recovered / Resolved	Mild	Probably Related	None	No
B0085	Group B4	A/Sing MAP, 10 ug	1	Headache	09-JUN-2018	22:00	10-JUN-2018	08:00	Recovered / Resolved	Moderate	Possibly Related	Concomitant Medication	No
B0085	Group B4	A/Sing MAP, 10 ug	2	Application site erythema -MAP site 2,3	10-JUN-2018	UK:UK	16-JUN-2018	13:30	Recovered / Resolved	Mild	Definitely Related	None	No
B0085	Group B4	A/Sing MAP, 10 ug	3	MAP site 3 visibility	11-AUG-2018	UK:UK	06-SEP-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0086	Group B9	A/Sing IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
B0087	Group B7	Placebo MAP	1	URTI	03-JUL-2018	07:00	28-JUL-2018	14:32	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
B0087	Group B7	Placebo MAP	2	Headache	30-JUN-2018	UK:UK	30-JUN-2018	UK:UK	Recovered / Resolved	Mild	Not Related	Concomitant Medication	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0088	Group B9	A/Sing IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
B0089	Group B5	A/Sing MAP, 5 ug	1	MAP 2 Erythema	12-JUN-2018	08:55	14-JUL-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
B0090	Group B6	A/Sing MAP, 2.5 ug	1	Flu - like symptom	11-JUN-2018	UK:UK	16-JUN-2018	06:00	Recovered / Resolved	Mild	Possibly Related	None	No
B0090	Group B6	A/Sing MAP, 2.5 ug	2	Secondary Hyperalgesia	10-JUN-2018	07:30	10-JUN-2018	08:00	Recovered / Resolved	Mild	Possibly Related	None	No
B0090	Group B6	A/Sing MAP, 2.5 ug	4	MAP itchiness	09-JUN-2018	12:48	09-JUN-2018	14:05	Recovered / Resolved	Moderate	Probably Related	Concomitant Medication	No
B0091	Group B8	A/Sing MAP, 15 ug	1	MAP reaction 1,2,3 Erythema	12-JUN-2018	13:06	16-JUN-2018	10:02	Recovered / Resolved	Mild	Probably Related	None	No
B0091	Group B8	A/Sing MAP, 15 ug	2	Flu like symptom	11-JUN-2018	09:00	11-JUN-2018	17:00	Recovered / Resolved	Mild	Possibly Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0091	Group B8	A/Sing MAP, 15 ug	3	Headache	13-JUN-2018	19:36	13-JUN-2018	20:40	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
B0091	Group B8	A/Sing MAP, 15 ug	4	MAP sites visibility 1,2,3	08-AUG-2018	10:02			Not recovered / Not resolved	Mild	Definitely Related	None	No
B0092	Group B4	A/Sing MAP, 10 ug	1	MAP 1,3 reaction Erythema	12-JUN-2018	10:16	30-JUN-2018	12:05	Recovered / Resolved	Mild	Probably Related	None	No
B0092	Group B4	A/Sing MAP, 10 ug	2	MAP 1,3 Visibility	02-AUG-2018	08:12	25-SEP-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0092	Group B4	A/Sing MAP, 10 ug	4	Headache	15-JUN-2018	20:15	15-JUN-2018	21:30	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
B0093	Group B7	Placebo MAP		[No Treatment-Emergent Adverse Events Reported]									
B0094	Group B3	A/Sing MAP, 15 ug	1	MAP 1,2,3 - Erythema	10-JUN-2018	13:07	16-JUN-2018	13:51	Recovered / Resolved	Mild	Probably Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0095	Group B9	A/Sing IM, 15 ug	1	Dizziness	13-JUN-2018	21:00	13-JUN-2018	21:05	Recovered / Resolved	Mild	Unlikely Related	None	No
B0096	Group B6	A/Sing MAP, 2.5 ug	1	Headache	09-JUN-2018	22:30	11-JUN-2018	18:00	Recovered / Resolved	Mild	Possibly Related	None	No
B0096	Group B6	A/Sing MAP, 2.5 ug	2	Nausea	09-JUN-2018	23:30	10-JUN-2018	10:30	Recovered / Resolved	Mild	Possibly Related	None	No
B0096	Group B6	A/Sing MAP, 2.5 ug	3	Myalgia	09-JUN-2018	17:00	20-JUN-2018	UK:UK	Recovered / Resolved	Moderate	Probably Related	None	No
B0096	Group B6	A/Sing MAP, 2.5 ug	4	MAP 1 Erythema	12-JUN-2018	12:29	16-JUN-2018	13:35	Recovered / Resolved	Mild	Probably Related	None	No
B0096	Group B6	A/Sing MAP, 2.5 ug	5	MAP 1 visibility	08-AUG-2018	13:48	28-AUG-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
B0097	Group B5	A/Sing MAP, 5 ug		[No Treatment-Emergent Adverse Events Reported]									

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0098	Group B7	Placebo MAP	1	Nausea	09-JUN-2018	13:40	09-JUN-2018	14:41	Recovered / Resolved	Mild	Possibly Related	None	No
B0099	Group B4	A/Sing MAP, 10 ug	2	URTI	26-JUL-2018	16:00	08-AUG-2018	UK:UK	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
B0100	Group B8	A/Sing MAP, 15 ug	1	Headache	09-JUN-2018	16:00	09-JUN-2018	20:30	Recovered / Resolved	Mild	Possibly Related	Concomitant Medication	No
B0100	Group B8	A/Sing MAP, 15 ug	2	MAP site reaction 1,2,3 Erythema and Oedema	10-JUN-2018	13:30	08-AUG-2018	15:23	Recovered / Resolved	Mild	Probably Related	None	No
B0101	Group B3	A/Sing MAP, 15 ug	1	MAP reaction 1,2,3 - Erythema	12-JUN-2018	12:34	30-JUN-2018	13:12	Recovered / Resolved	Mild	Probably Related	None	No
B0101	Group B3	A/Sing MAP, 15 ug	2	Rhinitis	15-JUN-2018	09:00	15-JUN-2018	16:00	Recovered / Resolved	Mild	Unlikely Related	None	No
B0102	Group B8	A/Sing MAP, 15 ug	1	MAP reaction 1,2,3 - Erythema	12-JUN-2018	14:24	23-JUN-2018	11:23	Recovered / Resolved	Mild	Probably Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0103	Group B5	A/Sing MAP, 5 ug	1	Pruritus Left forearm	14-JUN-2018	07:58	29-JUN-2018	08:00	Recovered / Resolved	Mild	Possibly Related	None	No
B0104	Group B3	A/Sing MAP, 15 ug	1	MAP 1,2,3 - Erythema	12-JUN-2018	14:29	16-JUN-2018	16:55	Recovered / Resolved	Mild	Probably Related	None	No
B0104	Group B3	A/Sing MAP, 15 ug	2	Musculoskeletal chest pain	16-JUN-2018	14:00	16-JUN-2018	17:30	Recovered / Resolved	Mild	Unlikely Related	Other ECG performed	No
B0104	Group B3	A/Sing MAP, 15 ug	3	MAP site 1,2,3 reaction visibility	10-AUG-2018	09:30	10-SEP-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
B0105	Group B9	A/Sing IM, 15 ug	1	Dry Cough	12-JUN-2018	07:00	14-JUN-2018	14:00	Recovered / Resolved	Mild	Possibly Related	None	No
B0105	Group B9	A/Sing IM, 15 ug	2	Myalgia IP arm	10-JUN-2018	UK:UK	13-JUN-2018	08:00	Recovered / Resolved	Mild	Possibly Related	None	No
B0105	Group B9	A/Sing IM, 15 ug	3	Upper Respiratory Tract Infection	29-JUN-2018	08:00	07-JUL-2018	UK:UK	Recovered / Resolved	Mild	Not Related	Concomitant Medication	No
B0106	Group B4	A/Sing MAP, 10 ug	1	Upper Respiratory Tract Infection	13-JUN-2018	08:00	18-JUN-2018	UK:UK	Recovered / Resolved	Mild	Not Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0106	Group B4	A/Sing MAP, 10 ug	2	MAP 2,3 - Erythema	12-JUN-2018	12:16	16-JUN-2018	15:52	Recovered / Resolved	Mild	Probably Related	None	No
B0107	Group B6	A/Sing MAP, 2.5 ug	1	MAP reaction site 2,3 - Erythema	12-JUN-2018	11:00	16-JUN-2018	09:58	Recovered / Resolved	Mild	Probably Related	None	No
B0107	Group B6	A/Sing MAP, 2.5 ug	2	MAP sites 1,2,3 visible	08-AUG-2018	17:48	14-SEP-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0108	Group B7	Placebo MAP	[No Treatment-Emergent Adverse Events Reported]										
B0109	Group B6	A/Sing MAP, 2.5 ug	1	MAP #2 and #3 visibility	15-AUG-2018	UK:UK	28-AUG-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0110	Group B3	A/Sing MAP, 15 ug	1	MAP 1,2,3 reaction - Erythema	19-JUN-2018	13:18	30-AUG-2018	13:16	Recovered / Resolved	Mild	Probably Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0111	Group B8	A/Sing MAP, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
B0112	Group B4	A/Sing MAP, 10 ug	1	MAP reaction sites 2,3 -Erythema	19-JUN-2018	11:55	07-JUL-2018	11:40	Recovered / Resolved	Mild	Definitely Related	None	No
B0112	Group B4	A/Sing MAP, 10 ug	2	MAP sites Visibility 2,3	15-AUG-2018	13:47	13-SEP-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0113	Group B5	A/Sing MAP, 5 ug	1	Headache	17-JUN-2018	16:00	19-JUN-2018	17:00	Recovered / Resolved	Mild	Unlikely Related	None	No
B0113	Group B5	A/Sing MAP, 5 ug	2	Headache	06-JUL-2018	07:00	06-JUL-2018	09:00	Recovered / Resolved	Mild	Unlikely Related	None	No
B0114	Group B7	Placebo MAP	1	Intermittent Headache	17-JUN-2018	08:00	22-JUN-2018	16:30	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No
B0114	Group B7	Placebo MAP	3	Insect bite - Right upper arm	16-JUN-2018	20:00	09-JUL-2018	11:28	Recovered / Resolved	Mild	Not Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0115	Group B9	A/Sing IM, 15 ug	1	URTI	02-JUL-2018	UK:UK	06-JUL-2018	UK:UK	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
B0116	Group B7	Placebo MAP	1	MAP sites - All three sites - Itchiness	18-JUN-2018	21:30	18-JUN-2018	23:00	Recovered / Resolved	Mild	Definitely Related	None	No
B0116	Group B7	Placebo MAP	2	Headache	20-JUN-2018	10:30	20-JUN-2018	23:30	Recovered / Resolved	Mild	Unlikely Related	None	No
B0116	Group B7	Placebo MAP	3	Headache	05-JUL-2018	10:00	05-JUL-2018	23:00	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
B0117	Group B9	A/Sing IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
B0118	Group B6	A/Sing MAP, 2.5 ug	1	Vasovagal Syncope	16-JUN-2018	13:02	16-JUN-2018	13:40	Recovered / Resolved	Moderate	Unlikely Related	Other Juice and Museli bar. Dose interrupted	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0118	Group B6	A/Sing MAP, 2.5 ug	2	Headache	16-JUN-2018	13:10	05-JUL-2018	20:00	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No
B0118	Group B6	A/Sing MAP, 2.5 ug	3	Nausea	18-JUN-2018	18:48	18-JUN-2018	19:50	Recovered / Resolved	Mild	Possibly Related	None	No
B0118	Group B6	A/Sing MAP, 2.5 ug	7	MAP site #2 visibility	15-AUG-2018	13:17	09-OCT-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0119	Group B4	A/Sing MAP, 10 ug	3	Gastroenteritis	21-JUN-2018	10:00	21-JUN-2018	16:00	Recovered / Resolved	Mild	Not Related	None	No
B0119	Group B4	A/Sing MAP, 10 ug	5	MAP 1,3 visibility	15-AUG-2018	14:14	27-AUG-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
B0120	Group B3	A/Sing MAP, 15 ug	1	MAP site reaction 1,2,3 - Erythema and MAP 2,3 Tenderness	19-JUN-2018	13:38	07-JUL-2018	14:00	Recovered / Resolved	Mild	Definitely Related	None	No
B0120	Group B3	A/Sing MAP, 15 ug	2	MAP site 1,2,3 visibility	07-JUL-2018	14:00	29-AUG-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0121	Group B8	A/Sing MAP, 15 ug	1	MAP 1,2,3 reaction - Erythema, tenderness and induration	19-JUN-2018	14:00	08-AUG-2018	09:40	Recovered / Resolved	Mild	Probably Related	None	No
B0121	Group B8	A/Sing MAP, 15 ug	3	Upper Respiratory Tract Infection	16-JUN-2018	18:00	18-JUN-2018	05:10	Recovered / Resolved	Mild	Not Related	None	No
B0121	Group B8	A/Sing MAP, 15 ug	4	Nausea	18-JUN-2018	05:00	18-JUN-2018	05:10	Recovered / Resolved	Mild	Possibly Related	None	No
B0122	Group B5	A/Sing MAP, 5 ug	1	MAP site 2 - Itching	18-JUN-2018	06:00	21-JUN-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0122	Group B5	A/Sing MAP, 5 ug	2	MAP reaction site 2 - Erythema, oedema + induration	19-JUN-2018	12:12	12-JUL-2018	09:00	Recovered / Resolved	Mild	Definitely Related	None	No
B0122	Group B5	A/Sing MAP, 5 ug	3	Pharyngitis	22-JUN-2018	06:00	24-JUN-2018	07:00	Recovered / Resolved	Mild	Possibly Related	None	No
B0122	Group B5	A/Sing MAP, 5 ug	4	MAP site 2 reaction Visibility	15-AUG-2018	14:07	28-AUG-2018	16:13	Recovered / Resolved	Mild	Definitely Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0123	Group B6	A/Sing MAP, 2.5 ug	1	Headache	17-JUN-2018	11:02	18-JUN-2018	12:30	Recovered / Resolved	Mild	Unlikely Related	None	No
B0123	Group B6	A/Sing MAP, 2.5 ug	3	Upper Respiratory Tract Infection	04-JUL-2018	22:00	08-JUL-2018	09:00	Recovered / Resolved	Mild	Not Related	None	No
B0124	Group B4	A/Sing MAP, 10 ug	1	Headache	16-JUN-2018	14:30	17-JUN-2018	09:00	Recovered / Resolved	Mild	Possibly Related	None	No
B0124	Group B4	A/Sing MAP, 10 ug	2	MAP reaction sites 2,3 - Erythema, oedema, induration	19-JUN-2018	14:40	21-JUL-2018	15:17	Recovered / Resolved	Mild	Definitely Related	None	No
B0124	Group B4	A/Sing MAP, 10 ug	3	Headache	21-JUN-2018	07:00	23-JUN-2018	18:00	Recovered / Resolved	Moderate	Unlikely Related	Concomitant Medication	No
B0124	Group B4	A/Sing MAP, 10 ug	4	Contact dermatitis	25-JUN-2018	06:00	30-JUN-2018	UK:UK	Recovered / Resolved	Mild	Not Related	Concomitant Medication	No
B0124	Group B4	A/Sing MAP, 10 ug	5	MAP visibility site #2 and #3	15-AUG-2018	15:00	10-OCT-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0125	Group B7	Placebo MAP		[No Treatment-Emergent Adverse Events Reported]									
B0126	Group B3	A/Sing MAP, 15 ug	1	MAP Visibility 1,2,3	15-AUG-2018	15:15	24-AUG-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0127	Group B9	A/Sing IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
B0128	Group B5	A/Sing MAP, 5 ug	1	MAP site reaction site 2 - oedema	26-JUN-2018	12:03	11-AUG-2018	10:00	Recovered / Resolved	Mild	Definitely Related	None	No
B0128	Group B5	A/Sing MAP, 5 ug	2	MAP site 2 Visibility	22-AUG-2018	UK:UK	15-OCT-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B0129	Group B8	A/Sing MAP, 15 ug	1	MAP reaction site 1,2,3 erythema	24-JUN-2018	12:17	22-AUG-2018	11:11	Recovered / Resolved	Mild	Definitely Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0129	Group B8	A/Sing MAP, 15 ug	2	MAP reaction site 1,2,3 visibility	22-AUG-2018	11:11	29-OCT-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
B0130	Group B5	A/Sing MAP, 5 ug	1	MAP site 1 reaction - Erythema	26-JUN-2018	10:13	22-AUG-2018	10:20	Recovered / Resolved	Mild	Probably Related	None	No
B0130	Group B5	A/Sing MAP, 5 ug	2	Upper Respiratory Tract Infection	27-JUN-2018	11:00	29-JUN-2018	09:00	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
B0130	Group B5	A/Sing MAP, 5 ug	3	Upper Respiratory Tract Infection	10-JUL-2018	08:00	17-JUL-2018	08:30	Recovered / Resolved	Mild	Not Related	Concomitant Medication	No
B0130	Group B5	A/Sing MAP, 5 ug	4	MAP site 1 visibilty	22-AUG-2018	10:20	01-OCT-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
B0131	Group B8	A/Sing MAP, 15 ug	1	MAP reaction site 1,2,3 -Erythema extent, erythema, MAP reaction site #2 te	26-JUN-2018	13:36	10-AUG-2018	09:00	Recovered / Resolved	Mild	Probably Related	None	No
B0131	Group B8	A/Sing MAP, 15 ug	2	Right Temporomandibular junction pain	28-JUN-2018	21:40	28-JUN-2018	23:50	Recovered / Resolved	Mild	Unlikely Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0132	Group B6	A/Sing MAP, 2.5 ug	1	Nausea	26-JUN-2018	17:30	26-JUN-2018	18:00	Recovered / Resolved	Mild	Not Related	Other Urinalysis performed, Result normal	No
B0133	Group B4	A/Sing MAP, 10 ug		[No Treatment-Emergent Adverse Events Reported]									
B0134	Group B3	A/Sing MAP, 15 ug	1	MAP 2,3 Visibility	23-AUG-2018	09:23	30-AUG-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
B0135	Group B7	Placebo MAP	1	URTI	24-JUN-2018	09:00	30-JUN-2018	08:00	Recovered / Resolved	Mild	Not Related	None	No
B0136	Group B9	A/Sing IM, 15 ug	1	Cholecystitis	05-JUL-2018	20:00	22-AUG-2018	11:13	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0137	Group B8	A/Sing MAP, 15 ug	1	MAP 1,2,3 - Erythema	26-JUN-2018	10:21	13-JUL-2018	09:00	Recovered / Resolved	Mild	Probably Related	None	No
B0137	Group B8	A/Sing MAP, 15 ug	2	Upper Respiratory Tract Infection	09-JUL-2018	07:00	07-AUG-2018	10:00	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
B0138	Group B7	Placebo MAP	2	MAP Visibility 1,2,3	22-AUG-2018	13:26			Not recovered / Not resolved	Mild	Definitely Related	None	No
B0139	Group B4	A/Sing MAP, 10 ug		[No Treatment-Emergent Adverse Events Reported]									
B0140	Group B9	A/Sing IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0141	Group B3	A/Sing MAP, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
B0142	Group B5	A/Sing MAP, 5 ug	1	Medial Tibial Stress Syndrome (Shin Splints)	12-JUL-2018	15:00	11-AUG-2018	09:00	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No
B0142	Group B5	A/Sing MAP, 5 ug	2	MAP 1 Visibility	25-AUG-2018	11:55	25-SEP-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
B0143	Group B6	A/Sing MAP, 2.5 ug	1	Headache	23-JUN-2018	14:35	23-JUN-2018	UK:UK	Recovered / Resolved	Mild	Possibly Related	None	No
B0143	Group B6	A/Sing MAP, 2.5 ug	2	MAP site 3 reaction - Erythema Oedema induration	26-JUN-2018	12:08	30-JUN-2018	12:14	Recovered / Resolved	Mild	Definitely Related	None	No
B0143	Group B6	A/Sing MAP, 2.5 ug	3	Exacerbation of Left knee sprain	04-JUL-2018	11:30	17-SEP-2018	UK:UK	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0143	Group B6	A/Sing MAP, 2.5 ug	4	MAP 3 Visibility	22-AUG-2018	13:09			Not recovered / Not resolved	Mild	Probably Related	None	No
B0144	Group B6	A/Sing MAP, 2.5 ug	1	Dizziness	23-JUN-2018	14:03	23-JUN-2018	15:50	Recovered / Resolved	Mild	Unlikely Related	None	No
B0144	Group B6	A/Sing MAP, 2.5 ug	2	Nausea	23-JUN-2018	14:03	23-JUN-2018	15:50	Recovered / Resolved	Mild	Unlikely Related	None	No
B0144	Group B6	A/Sing MAP, 2.5 ug	3	Upper Respiratory Tract Infection	14-JUL-2018	10:00	18-JUL-2018	08:30	Recovered / Resolved	Mild	Not Related	Concomitant Medication	No
B0145	Group B3	A/Sing MAP, 15 ug	1	Nausea	24-JUN-2018	13:00	24-JUN-2018	13:05	Recovered / Resolved	Mild	Unlikely Related	None	No
B0145	Group B3	A/Sing MAP, 15 ug	2	MAP 1,2,3 reaction - Erythema & MAP 2 reaction - Erythema extent	26-JUN-2018	10:44	28-JUL-2018	09:00	Recovered / Resolved	Mild	Probably Related	None	No
B0145	Group B3	A/Sing MAP, 15 ug	3	Headache	27-JUN-2018	17:05	27-JUN-2018	17:10	Recovered / Resolved	Mild	Unlikely Related	None	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0146	Group B7	Placebo MAP	1	Headache	02-JUL-2018	15:35	02-JUL-2018	16:00	Recovered / Resolved	Mild	Unlikely Related	None	No
B0146	Group B7	Placebo MAP	2	Toothache	02-JUL-2018	15:28	02-JUL-2018	16:00	Recovered / Resolved	Mild	Not Related	None	No
B0147	Group B9	A/Sing IM, 15 ug		[No Treatment-Emergent Adverse Events Reported]									
B0148	Group B5	A/Sing MAP, 5 ug	1	Erythema site 1	28-JUN-2018	22:00	18-JUL-2018	10:20	Recovered / Resolved	Mild	Definitely Related	None	No
B0148	Group B5	A/Sing MAP, 5 ug	2	MAP 1 Visibility	27-AUG-2018	11:20	10-OCT-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
B0149	Group B8	A/Sing MAP, 15 ug		[No Treatment-Emergent Adverse Events Reported]									

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)

Listing 16.2.7.1
Adverse Events - CRF Data only

Part B

Random- isation Number	Group	Treatment	AE No.	Adverse Event Verbatim	Onset Date	Onset Time	End Date	End Time	Outcome	Maximum Severity	Relation- ship	Actions Taken	SAE
B0150	Group B4	A/Sing MAP, 10 ug	4	MAP site 1,2 visibility	28-AUG-2018	13:33	11-OCT-2018	UK:UK	Recovered / Resolved	Mild	Probably Related	None	No
B1019	Group B8	A/Sing MAP, 15 ug	1	MAP visibility 1,2,3	20-JUL-2018	13:49	27-AUG-2018	UK:UK	Recovered / Resolved	Mild	Definitely Related	None	No
B1076	Group B5	A/Sing MAP, 5 ug	1	MAP 1 reaction - Erythema	19-JUN-2018	12:39	23-JUN-2018	10:45	Recovered / Resolved	Mild	Definitely Related	None	No
B1080	Group B7	Placebo MAP	1	Right shoulder sprain	16-JUN-2018	19:00	04-AUG-2018	08:30	Recovered / Resolved	Moderate	Not Related	Concomitant Medication	No

Administration Site Key: FA = Forearm; UA= Upper arm

Treatments Part A: A1 = A/Sing MAP, 15 ug (FA); A2 = Afluria Quad IM (UA), 15 ug; A3 = Placebo MAP (FA); A4 = A/Sing Mono IM, 15 ug (UA)

Treatments Part B: B1 = A/Sing MAP, 15 ug (FA) with biopsy; B2 = Placebo MAP (FA) with biopsy

B3 = A/Sing MAP, 15 ug (FA); B4 = A/Sing MAP, 10 ug (FA); B5 = A/Sing MAP, 5 ug (FA); B6 = A/Sing MAP, 2.5 ug (FA)

B7 = Placebo MAP (FA); B8 = A/Sing MAP, 15 ug (UA); B9 = A/Sing IM, 15 ug, as 2018 Afluria Quad (UA)