

## **Electronic Supplementary Material 2**

### **Article Title**

Safety of Intranasal Quadrivalent Live Attenuated Influenza Vaccine (QLAIV) in Children and Adolescents: A Post Marketing Prospective Cohort Study in England in the 2014-15 season

### **Journal**

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**Supplementary Table 1.** Crude risks and incidence rates of AEs for total evaluable cohort (N=385), in patients with or without asthma

Targeted Event <sup>a</sup>	Patients with Asthma (N=85)			Patients without Asthma (N=299)		
	Incidence n (%) <sup>b</sup> 95%CI*	Total time at risk (weeks) <sup>c</sup>	Incidence rate per 1000 patient-weeks (95% CI)**	Incidence n (%) <sup>b</sup> 95%CI*	Total time at risk (weeks) <sup>c</sup>	Incidence rate per 1000 patient-weeks (95% CI)**
High temperature (i.e. greater than 38.0°C)	10 (11.8) [5.8, 20.6]	155.5	57.9 (30.1, 111.2) n=9	31 (10.4) [7.2, 14.4]	549.6	54.6 (38.2, 78.1) n=30
Nausea and vomiting	6 (7.1) [2.6, 14.7]	163.3	36.7 (16.5, 81.8) n=6	15 (5.0) [2.8, 8.1]	576.5	20.8 (11.8, 36.7) n=12
Generally feeling unwell (malaise)	21 (24.7) [16.0, 35.3]	135.8	132.6 (83.5, 210.4) n=18	66 (22.1) [17.5, 27.2]	494.2	121.4 (94.3, 156.4) n=60
Headache	13 (15.3) [8.4, 24.7]	147.7	81.2 (46.1, 143.0) n=12	25 (8.4) [5.5, 12.1]	560.4	41.0 (27.3, 61.8) n=23
Decreased appetite	9 (10.6) [5.0, 19.2]	156.5	51.1 (25.6, 102.2) n=8	44 (14.7) [10.9, 19.2]	529.0	73.7 (53.9, 100.9) n=39
Rash	0 (0.0)	170.0	-	8 (2.7) [1.2, 5.2]	585.6	12.0 (5.7, 25.1) n=7
Muscle pain or joint pain	8 (9.4) [4.2, 17.7]	156.8	38.3 (17.2, 85.2) n=6	14 (4.7) [2.6, 7.7]	579.9	22.4 (13.0, 38.6) n=13
Any of the following: Swelling of the face, lips or tongue, difficulty breathing, feeling of dizziness/light-headedness, general itchiness with a rash	2 (2.4) [0.3, 8.2]	166.1	12.0 (3.0, 48.1) n=2	3 (1.0) [0.2, 2.9]	593.5	5.1 (1.6, 15.7) n=3
Wheezing	8 (9.4) [4.2, 17.7]	159.6	50.1 (25.1, 100.2) n=8	1 (0.3) [0.1, 1.8]	596.1	1.7 (0.2, 11.9) n=1
Nasal congestion/runny nose	39 (45.9) [35.0, 57.0]	110.1	327.1 (235.9, 453.4) n=36	127 (42.5) [36.8, 48.3]	399.1	305.7 (256.0, 365.1) n=122
Mouth or throat pain	10 (11.8) [5.8, 20.6]	159.7	62.6 (33.7, 116.4) n=10	29 (9.7) [6.6, 13.6]	556.0	43.2 (28.9, 64.4) n=24
Cough	19 (22.4) [14.0, 32.7]	146.3	129.9 (82.8, 203.6) n=19	61 (20.4) [16.0, 25.4]	518.3	115.8 (89.9, 149.1) n=60
Nosebleed	3 (3.5) [0.7, 10.0]	165.8	18.1 (5.8, 56.1) n=3	6 (2.0) [0.7, 4.3]	588.1	10.2 (4.6, 22.7) n=6
Increased irritability (if the child is between two and four years; n=193)	3 (33.3) [7.5, 70.1]	14.1	213.2 (68.8, 661.0) n=3	41 (22.3) [16.5, 29.0]	298.9	117.1 (84.1, 163.1) n=35
Increased crying (if the child is between two and four years; n=193)	4 (44.4) [13.7, 78.8]	12.1	248.5 (80.2, 770.6) n=3	23 (12.5) [8.1, 18.2]	331.8	60.3 (38.9, 93.4) n=20

<sup>a</sup> Counts include events reported as free text; <sup>b</sup> denominator of total cohort with past medical history of asthma at risk at start; <sup>c</sup> denominator person-time censored at event ; \*CI: binomial exact methods; \*\*CI: poisson exact method