

Assessment of an optimized manufacturing process for inactivated quadrivalent influenza vaccine: a Phase III, randomized, double-blind, safety and immunogenicity study in children and adults

### Additional file 3

Medically-attended adverse events in and adults (18–49 years), children (3–17 years), and infants (6–35 months), during the entire study† (total vaccinated cohort)

<b>System Organ Class Preferred Term</b>	<b>Adults IIV4-I N=466 n; % (95% CI)</b>	<b>Adults IIV4 N=474 n; % (95% CI)</b>
At least one symptom	9; 15.0 (7.1, 26.6)	8; 13.3 (5.9, 24.6)
Immune system disorders (10021428) Allergy to arthropod bite (10058285) Hypersensitivity (10020751)	0; 0.0 (0.0, 6.0) 1; 1.7 (0.0, 8.9)	1; 1.7 (0.0, 8.9) 0; 0.0 (0.0, 6.0)
Infections and infestations (10021881) Bronchitis (10006451) Gastroenteritis (10017888) Nasopharyngitis (10028810) Otitis media (10033078) Sinusitis (10040753) Tonsillitis (10044008)	1; 1.7 (0.0, 8.9) 1; 1.7 (0.0, 8.9) 0; 0.0 (0.0, 6.0) 1; 1.7 (0.0, 8.9) 0; 0.0 (0.0, 6.0) 1; 1.7 (0.0, 8.9)	1; 1.7 (0.0, 8.9) 2; 3.3 (0.4, 11.5) 2; 3.3 (0.4, 11.5) 0; 0.0 (0.0, 6.0) 1; 1.7 (0.0, 8.9) 0; 0.0 (0.0, 6.0)
Injury, poisoning and procedural complications (10022117) Arthropod bite (10003399) Joint injury (10060820) Post procedural inflammation (10063101)	0; 0.0 (0.0, 6.0) 1; 1.7 (0.0, 8.9) 0; 0.0 (0.0, 6.0)	1; 1.7 (0.0, 8.9) 0; 0.0 (0.0, 6.0) 1; 1.7 (0.0, 8.9)
Musculoskeletal and connective tissue disorders (10028395) Back pain (10003988) Intervertebral disc protrusion (10050296) Spinal disorder (10061368)	1; 1.7 (0.0, 8.9) 1; 1.7 (0.0, 8.9) 1; 1.7 (0.0, 8.9)	1; 1.7 (0.0, 8.9) 0; 0.0 (0.0, 6.0) 0; 0.0 (0.0, 6.0)
	<b>Children IIV4-I N=466 n; % (95% CI)</b>	<b>Children IIV4 N=474 n; % (95% CI)</b>
At least one symptom	235; 50.4 (45.8, 55.1)	252; 53.2 (48.6, 57.7)

Blood and lymphatic system disorders (10005329) Lymphadenitis (10025188)	1; 0.2 (0.0, 1.2)	0; 0.0 (0.0, 0.8)
Congenital, familial and genetic disorders (10010331) Cryptorchism (10011498)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Ear and labyrinth disorders (10013993) Ear pain (10014020) Middle ear inflammation (10065838)	1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2)	1; 0.2 (0.0, 1.2) 0; 0.0 (0.0, 0.8)
Eye disorders (10015919) Conjunctivitis allergic (10010744)	1; 0.2 (0.0, 1.2)	0; 0.0 (0.0, 0.8)
Gastrointestinal disorders (10017947) Anal fissure (10002153) Apthous stomatitis (10002958) Constipation (10010774) Diarrhoea (10012735) Enteritis (10014866) Inguinal hernia (10022016) Stomatitis (10042128) Teething (10043183) Tooth disorder (10044034) Toothache (10044055) Umbilical hernia (10045458) Vomiting (10047700)	0; 0.0 (0.0, 0.8) 0; 0.0 (0.0, 0.8) 1; 0.2 (0.0, 1.2) 3; 0.6 (0.1, 1.9) 2; 0.4 (0.1, 1.5) 0; 0.0 (0.0, 0.8) 2; 0.4 (0.1, 1.5) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 4; 0.9 (0.2, 2.2)	1; 0.2 (0.0, 1.2) 2; 0.4 (0.1, 1.5) 1; 0.2 (0.0, 1.2) 9; 1.9 (0.9, 3.6) 2; 0.4 (0.1, 1.5) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 2; 0.4 (0.1, 1.5) 3; 0.6 (0.1, 1.8) 0; 0.0 (0.0, 0.8) 6; 1.3 (0.5, 2.7)
General disorders and administration site conditions (10018065) Inflammation (10061218) Pain (10033371) Pyrexia (10037660)	1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 21; 4.5 (2.8, 6.8)	0; 0.0 (0.0, 0.8) 0; 0.0 (0.0, 0.8) 20; 4.2 (2.6, 6.4)
Immune system disorders (10021428) Food allergy (10016946) Hypersensitivity (10020751)	0; 0.0 (0.0, 0.8) 0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2)
Infections and infestations (10021881) Acarodermatitis (10063409) Acute tonsillitis (10001093) Adenovirus infection (10060931) Bronchiolitis (10006448) Bronchitis (10006451) Bronchitis viral (10053160) Bronchopneumonia (10006469) Candida infection (10074170) Candida nappy rash (10007135) Conjunctivitis (10010741) Croup infectious (10011416) Dysentery (10051402) Ear infection (10014011) Enterobiasis (10014881) Epstein-barr virus infection (10015108) Exanthema subitum (10015586) Febrile infection (10051998) Fungal infection (10017533) Fungal skin infection (10017543)	1; 0.2 (0.0, 1.2) 0; 0.0 (0.0, 0.8) 0; 0.0 (0.0, 0.8) 7; 1.5 (0.6, 3.1) 46; 9.9 (7.3, 12.9) 0; 0.0 (0.0, 0.8) 6; 1.3 (0.5, 2.8) 2; 0.4 (0.1, 1.5) 0; 0.0 (0.0, 0.8) 17; 3.6 (2.1, 5.8) 2; 0.4 (0.1, 1.5) 0; 0.0 (0.0, 0.8) 11; 2.4 (1.2, 4.2) 0; 0.0 (0.0, 0.8) 0; 0.0 (0.0, 0.8) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 2; 0.4 (0.1, 1.5) 2; 0.4 (0.1, 1.5) 2; 0.4 (0.1, 1.5)	0; 0.0 (0.0, 0.8) 2; 0.4 (0.1, 1.5) 1; 0.2 (0.0, 1.2) 9; 1.9 (0.9, 3.6) 57; 12.0 (9.2, 15.3) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 0; 0.0 (0.0, 0.8) 1; 0.2 (0.0, 1.2) 16; 3.4 (1.9, 5.4) 0; 0.0 (0.0, 0.8) 2; 0.4 (0.1, 1.5) 15; 3.2 (1.8, 5.2) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 0; 0.0 (0.0, 0.8) 0; 0.0 (0.0, 0.8) 1; 0.2 (0.0, 1.2)

Gastroenteritis (10017888)	29; 6.2 (4.2, 8.8)	34; 7.2 (5.0, 9.9)
Gastroenteritis viral (10017918)	1; 0.2 (0.0, 1.2)	0; 0.0 (0.0, 0.8)
Gianotti-crostiti syndrome (10053842)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Giardiasis (10018262)	1; 0.2 (0.0, 1.2)	0; 0.0 (0.0, 0.8)
Gingivitis (10018292)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Haemophilus infection (10061190)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Hand-foot-and-mouth disease (10019113)	3; 0.6 (0.1, 1.9)	5; 1.1 (0.3, 2.4)
Herpangina (10019936)	4; 0.9 (0.2, 2.2)	4; 0.8 (0.2, 2.1)
Herpes virus infection (10019973)	1; 0.2 (0.0, 1.2)	1; 0.2 (0.0, 1.2)
Hordeolum (10020377)	1; 0.2 (0.0, 1.2)	1; 0.2 (0.0, 1.2)
Impetigo (10021531)	1; 0.2 (0.0, 1.2)	1; 0.2 (0.0, 1.2)
Laryngitis (10023874)	3; 0.6 (0.1, 1.9)	8; 1.7 (0.7, 3.3)
Lice infestation (10024424)	1; 0.2 (0.0, 1.2)	0; 0.0 (0.0, 0.8)
Lower respiratory tract infection (10024968)	5; 1.1 (0.3, 2.5)	1; 0.2 (0.0, 1.2)
Molluscum contagiosum (10027807)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Myringitis (10061302)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Nasopharyngitis (10028810)	27; 5.8 (3.9, 8.3)	30; 6.3 (4.3, 8.9)
Oral candidiasis (10030963)	1; 0.2 (0.0, 1.2)	2; 0.4 (0.1, 1.5)
Oral fungal infection (10061324)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Oral herpes (10067152)	2; 0.4 (0.1, 1.5)	1; 0.2 (0.0, 1.2)
Otitis externa (10033072)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Otitis media (10033078)	8; 1.7 (0.7, 3.4)	8; 1.7 (0.7, 3.3)
Otitis media acute (10033079)	19; 4.1 (2.5, 6.3)	14; 3.0 (1.6, 4.9)
Pharyngitis (10034835)	13; 2.8 (1.5, 4.7)	7; 1.5 (0.6, 3.0)
Pharyngotonsillitis (10049140)	3; 0.6 (0.1, 1.9)	3; 0.6 (0.1, 1.8)
Pneumonia (10035664)	3; 0.6 (0.1, 1.9)	4; 0.8 (0.2, 2.1)
Pneumonia respiratory syncytial viral (10035732)	1; 0.2 (0.0, 1.2)	0; 0.0 (0.0, 0.8)
Pseudocroup (10050187)	1; 0.2 (0.0, 1.2)	1; 0.2 (0.0, 1.2)
Rash pustular (10037888)	1; 0.2 (0.0, 1.2)	0; 0.0 (0.0, 0.8)
Respiratory syncytial virus bronchiolitis (10038718)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Respiratory tract infection (10062352)	6; 1.3 (0.5, 2.8)	7; 1.5 (0.6, 3.0)
Respiratory tract infection viral (10062106)	2; 0.4 (0.1, 1.5)	5; 1.1 (0.3, 2.4)
Rhinitis (10039083)	6; 1.3 (0.5, 2.8)	9; 1.9 (0.9, 3.6)
Rhinotracheitis (10051497)	3; 0.6 (0.1, 1.9)	5; 1.1 (0.3, 2.4)
Roseola (10039222)	2; 0.4 (0.1, 1.5)	5; 1.1 (0.3, 2.4)
Scarlet fever (10039587)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Sinobronchitis (10048979)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Sinusitis (10040753)	2; 0.4 (0.1, 1.5)	0; 0.0 (0.0, 0.8)
Streptococcal infection (10061372)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Tonsillitis (10044008)	6; 1.3 (0.5, 2.8)	7; 1.5 (0.6, 3.0)
Tracheitis (10044302)	6; 1.3 (0.5, 2.8)	8; 1.7 (0.7, 3.3)
Upper respiratory tract infection (10046306)	60; 12.9 (10.0, 16.3)	66; 13.9 (10.9, 17.4)
Urinary tract infection (10046571)	2; 0.4 (0.1, 1.5)	2; 0.4 (0.1, 1.5)
Varicella (10046980)	2; 0.4 (0.1, 1.5)	4; 0.8 (0.2, 2.1)
Viral infection (10047461)	10; 2.1 (1.0, 3.9)	15; 3.2 (1.8, 5.2)
Viral rash (10047476)	2; 0.4 (0.1, 1.5)	2; 0.4 (0.1, 1.5)
Viral tonsillitis (10047480)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Injury, poisoning and procedural complications (10022117)		
Arthropod bite (10003399)	3; 0.6 (0.1, 1.9)	1; 0.2 (0.0, 1.2)
Contusion (10050584)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Face injury (10050392)	1; 0.2 (0.0, 1.2)	0; 0.0 (0.0, 0.8)
Foreign body (10070245)	1; 0.2 (0.0, 1.2)	0; 0.0 (0.0, 0.8)
Hair injury (10074924)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Head injury (10019196)	1; 0.2 (0.0, 1.2)	1; 0.2 (0.0, 1.2)
Injury (10022116)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)

Joint dislocation (10023204) Limb injury (10061225) Lip injury (10055082) Thermal burn (10053615) Traumatic haematoma (10044522) Wound dehiscence (10048031)	0; 0.0 (0.0, 0.8) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 2; 0.4 (0.1, 1.5) 1; 0.2 (0.0, 1.2) 0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2) 0; 0.0 (0.0, 0.8) 0; 0.0 (0.0, 0.8) 0; 0.0 (0.0, 0.8) 0; 0.0 (0.0, 0.8) 1; 0.2 (0.0, 1.2)
Metabolism and nutrition disorders (10027433) Dehydration (10012174) Iron deficiency (10022970) Lactose intolerance (10023681) Weight gain poor (10047897)	1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 0; 0.0 (0.0, 0.8)	0; 0.0 (0.0, 0.8) 0; 0.0 (0.0, 0.8) 0; 0.0 (0.0, 0.8) 1; 0.2 (0.0, 1.2)
Musculoskeletal and connective tissue disorders (10028395) Synovitis (10042868)	1; 0.2 (0.0, 1.2)	1; 0.2 (0.0, 1.2)
Neoplasms benign, malignant and unspecified (10029104) Melanocytic naevus (10027145)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Nervous system disorders (10029205) Febrile convulsion (10016284)	0; 0.0 (0.0, 0.8)	1; 0.2 (0.0, 1.2)
Psychiatric disorders (10037175) Bruxism (10006514) Insomnia (10022437) Irritability (10022998) Sleep disorder (10040984)	1; 0.2 (0.0, 1.2) 0; 0.0 (0.0, 0.8) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2)	0; 0.0 (0.0, 0.8) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 0; 0.0 (0.0, 0.8)
Reproductive system and breast disorders (10038604) Balanoposthitis (10004078)	2; 0.4 (0.1, 1.5)	0; 0.0 (0.0, 0.8)
Respiratory, thoracic and mediastinal disorders (10038738) Allergic bronchitis (10052613) Allergic cough (10053779) Asthma (10003553) Asthmatic crisis (10064823) Atelectasis (10003598) Bronchial hyperreactivity (10066091) Bronchospasm (10006482) Cough (10011224) Epistaxis (10015090) Oropharyngeal pain (10068319) Rhinitis allergic (10039085) Rhinorrhoea (10039101)	1; 0.2 (0.0, 1.2) 0; 0.0 (0.0, 0.8) 4; 0.9 (0.2, 2.2) 1; 0.2 (0.0, 1.2) 0; 0.0 (0.0, 0.8) 5; 1.1 (0.3, 2.5) 11; 2.4 (1.2, 4.2) 11; 2.4 (1.2, 4.2) 0; 0.0 (0.0, 0.8) 1; 0.2 (0.0, 1.2) 0; 0.0 (0.0, 0.8) 3; 0.6 (0.1, 1.9)	0; 0.0 (0.0, 0.8) 2; 0.4 (0.1, 1.5) 3; 0.6 (0.1, 1.8) 0; 0.0 (0.0, 0.8) 1; 0.2 (0.0, 1.2) 7; 1.5 (0.6, 3.0) 9; 1.9 (0.9, 3.6) 14; 3.0 (1.6, 4.9) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2)
Skin and subcutaneous tissue disorders (10040785) Dermatitis (10012431) Dermatitis allergic (10012434) Dermatitis atopic (10012438) Dermatitis diaper (10012444) Dry skin (10013786) Eczema (10014184) Idiopathic urticaria (10021247) Nail dystrophy (10028698) Neurodermatitis (10029263) Rash (10037844)	4; 0.9 (0.2, 2.2) 2; 0.4 (0.1, 1.5) 0; 0.0 (0.0, 0.8) 7; 1.5 (0.6, 3.1) 1; 0.2 (0.0, 1.2) 6; 1.3 (0.5, 2.8) 0; 0.0 (0.0, 0.8) 0; 0.0 (0.0, 0.8) 1; 0.2 (0.0, 1.2) 2; 0.4 (0.1, 1.5)	1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 2; 0.4 (0.1, 1.5) 3; 0.6 (0.1, 1.8) 0; 0.0 (0.0, 0.8) 4; 0.8 (0.2, 2.1) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2) 0; 0.0 (0.0, 0.8) 7; 1.5 (0.6, 3.0)

Skin fissures (10040849) Skin hyperpigmentation (10040865) Urticaria (10046735)	1; 0.2 (0.0, 1.2) 0; 0.0 (0.0, 0.8) 2; 0.4 (0.1, 1.5)	0; 0.0 (0.0, 0.8) 1; 0.2 (0.0, 1.2) 1; 0.2 (0.0, 1.2)
	<b>Infants IIV4-I N=410 n; % (95% CI)</b>	<b>Infants IIV4 N=411 n; % (95% CI)</b>
At least one symptom	59; 14.4 (11.1, 18.2)	52; 12.7 (9.6, 16.3)
Blood and lymphatic system disorders (10005329) Lymphadenitis (10025188) Lymphadenopathy (10025197)	1; 0.2 (0.0, 1.4) 1; 0.2 (0.0, 1.4)	0; 0.0 (0.0, 0.9) 0; 0.0 (0.0, 0.9)
Ear and labyrinth disorders (10013993) Otorrhoea (10033101)	0; 0.0 (0.0, 0.9)	1; 0.2 (0.0, 1.3)
Gastrointestinal disorders (10017947) Abdominal pain (10000081) Constipation (10010774) Inguinal hernia (10022016) Oral pain (10031009) Stomatitis (10042128) Vomiting (10047700)	2; 0.5 (0.1, 1.8) 1; 0.2 (0.0, 1.4) 0; 0.0 (0.0, 0.9) 0; 0.0 (0.0, 0.9) 0; 0.0 (0.0, 0.9) 2; 0.5 (0.1, 1.8)	0; 0.0 (0.0, 0.9) 1; 0.2 (0.0, 1.3) 1; 0.2 (0.0, 1.3) 1; 0.2 (0.0, 1.3) 1; 0.2 (0.0, 1.3) 0; 0.0 (0.0, 0.9)
General disorders and administration site conditions (10018065) Chest pain (10008479) Pyrexia (10037660)	0; 0.0 (0.0, 0.9) 1; 0.2 (0.0, 1.4)	1; 0.2 (0.0, 1.3) 1; 0.2 (0.0, 1.3)
Immune system disorders (10021428) Food allergy (10016946) Milk allergy (10027633)	0; 0.0 (0.0, 0.9) 0; 0.0 (0.0, 0.9)	1; 0.2 (0.0, 1.3) 1; 0.2 (0.0, 1.3)
Infections and infestations (10021881) Acute tonsillitis (10001093) Bronchitis (10006451) Bronchopneumonia (10006469) Cellulitis (10007882) Conjunctivitis (10010741) Cystitis (10011781) Ear infection (10014011) Enterovirus infection (10014909) Gastroenteritis (10017888) Herpangina (10019936) Herpes simplex (10019948) Impetigo (10021531) Laryngitis (10023874) Meningitis viral (10027260) Molluscum contagiosum (10027807) Nasopharyngitis (10028810) Oral herpes (10067152) Otitis externa (10033072) Otitis media (10033078)	1; 0.2 (0.0, 1.4) 7; 1.7 (0.7, 3.5) 1; 0.2 (0.0, 1.4) 7; 1.7 (0.7, 3.5) 1; 0.2 (0.0, 1.4) 0; 0.0 (0.0, 0.9) 1; 0.2 (0.0, 1.4) 0; 0.0 (0.0, 0.9) 0; 0.0 (0.0, 0.9) 1; 0.2 (0.0, 1.4) 1; 0.2 (0.0, 1.4) 1; 0.2 (0.0, 1.4) 0; 0.0 (0.0, 0.9) 1; 0.2 (0.0, 1.4) 2; 0.5 (0.1, 1.8) 2; 0.5 (0.1, 1.8) 0; 0.0 (0.0, 0.9) 1; 0.2 (0.0, 1.4) 2; 0.5 (0.1, 1.8)	1; 0.2 (0.0, 1.3) 4; 1.0 (0.3, 2.5) 0; 0.0 (0.0, 0.9) 4; 1.0 (0.3, 2.5) 0; 0.0 (0.0, 0.9) 1; 0.2 (0.0, 1.3) 0; 0.0 (0.0, 0.9) 1; 0.2 (0.0, 1.3) 3; 0.7 (0.2, 2.1) 0; 0.0 (0.0, 0.9) 0; 0.0 (0.0, 0.9) 5; 1.2 (0.4, 2.8) 1; 0.2 (0.0, 1.3) 1; 0.2 (0.0, 1.3) 0; 0.0 (0.0, 0.9) 2; 0.5 (0.1, 1.7) 2; 0.5 (0.1, 1.7) 0; 0.0 (0.0, 0.9) 1; 0.2 (0.0, 1.3)

Otitis media acute (10033079)	2; 0.5 (0.1, 1.8)	1; 0.2 (0.0, 1.3)
Paronychia (10034016)	1; 0.2 (0.0, 1.4)	0; 0.0 (0.0, 0.9)
Periporitis staphylogenes (10064163)	1; 0.2 (0.0, 1.4)	0; 0.0 (0.0, 0.9)
Pertussis (10034738)	1; 0.2 (0.0, 1.4)	0; 0.0 (0.0, 0.9)
Pharyngitis (10034835)	6; 1.5 (0.5, 3.2)	4; 1.0 (0.3, 2.5)
Pharyngitis streptococcal (10034839)	2; 0.5 (0.1, 1.8)	0; 0.0 (0.0, 0.9)
Pharyngotonsillitis (10049140)	2; 0.5 (0.1, 1.8)	2; 0.5 (0.1, 1.7)
Pseudocroup (10050187)	1; 0.2 (0.0, 1.4)	0; 0.0 (0.0, 0.9)
Respiratory tract infection (10062352)	0; 0.0 (0.0, 0.9)	1; 0.2 (0.0, 1.3)
Rhinitis (10039083)	1; 0.2 (0.0, 1.4)	5; 1.2 (0.4, 2.8)
Scarlet fever (10039587)	0; 0.0 (0.0, 0.9)	1; 0.2 (0.0, 1.3)
Sinusitis (10040753)	1; 0.2 (0.0, 1.4)	2; 0.5 (0.1, 1.7)
Tonsillitis (10044008)	3; 0.7 (0.2, 2.1)	2; 0.5 (0.1, 1.7)
Tooth abscess (10044016)	1; 0.2 (0.0, 1.4)	0; 0.0 (0.0, 0.9)
Tracheitis (10044302)	2; 0.5 (0.1, 1.8)	2; 0.5 (0.1, 1.7)
Upper respiratory tract infection (10046306)	4; 1.0 (0.3, 2.5)	8; 1.9 (0.8, 3.8)
Viral diarrhoea (10051511)	0; 0.0 (0.0, 0.9)	1; 0.2 (0.0, 1.3)
Viral infection (10047461)	3; 0.7 (0.2, 2.1)	0; 0.0 (0.0, 0.9)
Vulvitis (10047780)	1; 0.2 (0.0, 1.4)	0; 0.0 (0.0, 0.9)
Injury, poisoning and procedural complications (10022117)		
Arthropod bite (10003399)	1; 0.2 (0.0, 1.4)	1; 0.2 (0.0, 1.3)
Contusion (10050584)	1; 0.2 (0.0, 1.4)	1; 0.2 (0.0, 1.3)
Head injury (10019196)	0; 0.0 (0.0, 0.9)	1; 0.2 (0.0, 1.3)
Joint injury (10060820)	1; 0.2 (0.0, 1.4)	0; 0.0 (0.0, 0.9)
Laceration (10023572)	1; 0.2 (0.0, 1.4)	1; 0.2 (0.0, 1.3)
Ligament sprain (10024453)	0; 0.0 (0.0, 0.9)	1; 0.2 (0.0, 1.3)
Wound (10052428)	1; 0.2 (0.0, 1.4)	0; 0.0 (0.0, 0.9)
Musculoskeletal and connective tissue disorders (10028395)		
Neck pain (10028836)	1; 0.2 (0.0, 1.4)	0; 0.0 (0.0, 0.9)
Neoplasms benign, malignant and unspecified (10029104)		
Skin papilloma (10040907)	1; 0.2 (0.0, 1.4)	0; 0.0 (0.0, 0.9)
Nervous system disorders (10029205)		
Headache (10019211)	0; 0.0 (0.0, 0.9)	1; 0.2 (0.0, 1.3)
Syncope (10042772)	1; 0.2 (0.0, 1.4)	1; 0.2 (0.0, 1.3)
Renal and urinary disorders (10038359)		
Enuresis (10014928)	1; 0.2 (0.0, 1.4)	0; 0.0 (0.0, 0.9)
Respiratory, thoracic and mediastinal disorders (10038738)		
Bronchial hyperreactivity (10066091)	1; 0.2 (0.0, 1.4)	1; 0.2 (0.0, 1.3)
Bronchospasm (10006482)	0; 0.0 (0.0, 0.9)	1; 0.2 (0.0, 1.3)
Cough (10011224)	4; 1.0 (0.3, 2.5)	4; 1.0 (0.3, 2.5)
Dyspnoea (10013968)	1; 0.2 (0.0, 1.4)	0; 0.0 (0.0, 0.9)
Oropharyngeal pain (10068319)	0; 0.0 (0.0, 0.9)	2; 0.5 (0.1, 1.7)
Tonsillar hypertrophy (10044003)	0; 0.0 (0.0, 0.9)	1; 0.2 (0.0, 1.3)
Skin and subcutaneous tissue disorders (10040785)		
Dermatitis (10012431)	1; 0.2 (0.0, 1.4)	2; 0.5 (0.1, 1.7)
Dry skin (10013786)	1; 0.2 (0.0, 1.4)	0; 0.0 (0.0, 0.9)
Eczema (10014184)	1; 0.2 (0.0, 1.4)	0; 0.0 (0.0, 0.9)

IIV4-I, quadrivalent inactivated influenza vaccine manufacturing by investigational process; IIV4, licensed quadrivalent inactivated influenza vaccine; MAE, medically-attended adverse event; †including the allowed visit interval of up to 23 days post-vaccination for the adults and up to 42 days post-last vaccination for the children; N, number of subjects with  $\geq 1$  vaccine dose; n, number of participants reporting the MAE; CI, confidence interval