

Table 1: UK spontaneous suspected adverse drug reaction (ADR) reports concerning Pfizer-BioNTech COVID-19 vaccine batch **FF3319** and specific Medical Dictionary for Regulatory Activities (MedDRA) Preferred Terms (PTs) up to and including 14.09.2026, broken down into serious reports, and reports where the patient was hospitalised (as selected by the reporter via the Council for International Organizations of Medical Sciences (CIOMS) seriousness flag for hospitalisation).

Suspected ADR	Number of reports classified as serious	Number of reports where patient was hospitalised (CIOMS hospitalisation flag)	Total number of reports
Artery dissection	1	1	1
Dyspnoea exertional	1	0	2
Exercise tolerance decreased	2	1	2
Palpitations	114	24	133
Tachycardia	43	7	43
Thrombosis	9	1	9
Vasculitis	1	0	1

Table 2: UK spontaneous suspected adverse drug reaction (ADR) reports concerning Pfizer-BioNTech COVID-19 vaccine batch **FF3319** and specific Medical Dictionary for Regulatory Activities (MedDRA) Preferred Terms (PTs) 'Artery dissection' and 'Vasculitis' up to and including 14.09.2026, displaying date reports were initially received by the MHRA.

Suspected ADR	Date report was received by MHRA (MM/YYYY)	Number of reports
Artery dissection	10/2021	1
Vasculitis	08/2021	1

Table 3: UK spontaneous suspected adverse drug reaction (ADR) reports concerning Pfizer-BioNTech COVID-19 vaccine batch **FF3319** and specific Medical Dictionary for Regulatory Activities (MedDRA) Preferred Terms (PTs) up to and including 14.09.2026, broken down by patient sex.

Patient sex	Number of reports						
	Artery dissection	Dyspnoea exertional	Exercise tolerance decreased	Palpitations	Tachycardia	Thrombosis	Vasculitis
Female	1	2	1	76	21	3	0
Male	0	0	1	56	21	6	1
Unknown	0	0	0	1	1	0	0
Total	1	2	2	133	43	9	1

Table 4: UK spontaneous suspected adverse drug reaction (ADR) reports concerning Pfizer-BioNTech COVID-19 vaccine batch **FF3319** and specific Medical Dictionary for Regulatory Activities (MedDRA) Preferred Terms (PTs) up to and including 14.09.2026, broken down by patient age range.

Patient age range (years)	Number of reports						
	Artery dissection	Dyspnoea exertional	Exercise tolerance decreased	Palpitations	Tachycardia	Thrombosis	Vasculitis
0-9	0	0	0	0	0	0	0
10-19	0	0	0	8	7	0	0
20-29	0	1	0	36	9	3	1
30-39	1	1	2	55	20	3	0
40-49	0	0	0	14	2	2	0
50-59	0	0	0	6	2	0	0
60-69	0	0	0	1	1	0	0
70-79	0	0	0	0	0	0	0
80 and over	0	0	0	0	0	0	0
Unknown	0	0	0	13	2	1	0
Total	1	2	2	133	43	9	1