

Online Resource 11

Electronic Supplementary material

Article Title: Implementation and results of active vaccine safety monitoring during the COVID-19 pandemic in the UK: a regulatory perspective

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Commonly Reported Adverse Reactions (ADRs) in Pregnant Females

Supplementary Table 23. Most commonly reported ADRs by vaccine dose in the cohort of pregnant females.

Dose	Ranked ADR reported (MedDRA PT level)	Number of ADR reported (% of total ADRs per dose)	
First dose	Pain in extremity	302	(24.1)
	Fatigue	167	(13.3)
	Headache	134	(10.7)
	Pyrexia	74	(5.9)
	Myalgia	50	(4.0)
	Nausea	43	(3.4)
	Injection site pain	36	(2.9)
	Chills	35	(2.8)
	Pain	35	(2.8)
	Limb discomfort	34	(2.7)
	Total ADRs	1,255	
Second dose	Fatigue	74	(15.5)
	Headache	58	(12.2)
	Pain in extremity	54	(11.3)
	Pyrexia	33	(6.9)
	Nausea	23	(4.8)
	Pain	22	(4.6)
	Myalgia	21	(4.4)
	Chills	16	(3.4)
	Arthralgia	12	(2.5)
	Dizziness	11	(2.3)
	Total ADRs	476	
Third dose	Fatigue	17	(14.4)
	Pain in extremity	16	(13.6)

Headache	14	(11.9)
Pyrexia	8	(6.8)
Chills	7	(5.9)
Myalgia	5	(4.2)
Pain	5	(4.2)
Nausea	4	(3.4)
Diarrhoea	3	(2.5)
Dizziness	3	(2.5)
Influenza	3	(2.5)
Injection site pain	3	(2.5)
Total ADRs	118	

Abbreviations: *ADR* Adverse drug reaction, *MedDRA* Medical Dictionary for Regulatory Activities, *PT* preferred term