

**Table 6. Description of Missing Information**

Topic	Description
<b>Missing Information</b>	<b>Post Authorization Cases Evaluation (cumulative to 28 Feb 2021) Total Number of Cases in the Reporting Period (N=42086)</b>
Use in Pregnancy and lactation	<ul style="list-style-type: none"> <li>• Number of cases: 413<sup>a</sup> (0.98% of the total PM dataset); 84 serious and 329 non-serious;</li> <li>• Country of incidence: US (205), UK (64), Canada (31), Germany (30), Poland (13), Israel (11); Italy (9), Portugal (8), Mexico (6), Estonia, Hungary and Ireland, (5 each), Romania (4), Spain (3), Czech Republic and France (2 each), the remaining 10 cases were distributed among 10 other countries.</li> </ul> <p>Pregnancy cases: 274 cases including:</p> <ul style="list-style-type: none"> <li>• 270 mother cases and 4 foetus/baby cases representing <u>270 unique pregnancies</u> (the 4 foetus/baby cases were linked to 3 mother cases; 1 mother case involved twins).</li> <li>• Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and <u>normal outcome</u> (1 each). <u>No outcome was provided for 238 pregnancies</u> (note that 2 different outcomes were reported for each twin, and both were counted).</li> <li>• 146 non-serious mother cases reported exposure to vaccine in utero without the occurrence of any clinical adverse event. The exposure PTs coded to the PTs Maternal exposure during pregnancy (111), Exposure during pregnancy (29) and Maternal exposure timing unspecified (6). Trimester of exposure was reported in 21 of these cases: 1st trimester (15 cases), 2nd trimester (7), and 3rd trimester (2).</li> <li>• 124 mother cases, 49 non-serious and 75 serious, reported clinical events, which occurred in the vaccinated mothers. Pregnancy related events reported in these cases coded to the PTs <u>Abortion spontaneous</u> (25), Uterine contraction during pregnancy, Premature rupture of membranes, Abortion, Abortion missed, and <u>Foetal death</u> (1 each). Other clinical events which occurred in more than 5 cases coded to the PTs Headache (33), Vaccination site pain (24), Pain in extremity and Fatigue (22 each), Myalgia and Pyrexia (16 each), Chills (13) Nausea (12), Pain (11), Arthralgia (9), Lymphadenopathy and Drug ineffective (7 each), Chest pain, Dizziness and Asthenia (6 each), Malaise and COVID-19 (5 each). Trimester of exposure was reported in 22 of these cases: 1st trimester (19 cases), 2nd trimester (1 case), 3rd trimester (2 cases).</li> <li>• 4 serious foetus/baby cases reported the PTs Exposure during pregnancy, Foetal growth restriction, Maternal exposure during pregnancy, Premature baby (2 each), and <u>Death neonatal</u> (1). Trimester of exposure was reported for 2 cases (twins) as occurring during the 1st trimester.</li> </ul>