Supplemental Information

SUPPLEMENTAL TABLE 3 Outcomes for Sequential Analyses and Descriptive Monitoring Following COVID-19 Vaccination in the Vaccine Safety Datalink Outcome^a Sequential Analyses Risk Interval Setting ICD-10 Codes Medical Record Review E, I G04.00, G04.02 Acute disseminated 1-21 d Yes, prespecified^b encephalomyelitis Acute myocardial 1-21 d E, I 121 * No infarction 1-21 d K35.*, K36, K37, K38.8 **Appendicitis** E, I No Bell's palsy 1-21 d E. I. 0 G51.0 No Cerebral venous sinus 1-21 d E, I G08, 163.6, 167.6 Yes, prespecified^b thrombosis Convulsions or seizures 0-7 d, 0-21 d E, I R56.0*, R56.9 No Disseminated intravascular 1-21 d E, I Nο D65 coagulation Encephalitis, myelitis, or 1-21 d E, I G04.30, G04.32, G04.39, No encephalomyelitis G04.8*, G04.9*, G05.*, G37.4 Guillain-Barré syndrome 1-21 d E, I G61.0 Yes, prespecified^b Immune thrombocytopenia 1-21 d E. I. 0 D69.3 1-21 d E, I M30.3 Kawasaki disease Yes, post hoc Myocarditis or pericarditis 1-21 d E, I B33.22, B33.23, I30.*, I31.9, Yes, prespecified^b 140.*, 151.4 Pulmonary embolism 1-21 d E, I 126.* No E, I Stroke, hemorrhagic 1-21 d 160.*, 161.*, 162.* Yes, post hocb Stroke, ischemic 1-21 d E, I G45.8, G45.9, I63.* No Thrombosis with 1-21 d E, I Platelet count < 150 000 per No thrombocytopenia microliter and 1 of the syndrome following ICD-10 codes: G08, 163.6, 167.6, 174.0*, 174.1*, 174.3, 174.5, 174.8, 174.9, 181, 182.0, 182.890, K55.0*, N28.0 Thrombotic 1-21 d E, I M31.1 No thrombocytopenic purpura Transverse myelitis 1-21 d E, I G37.3 Yes, prespecified^b Venous thromboembolism 1-21 d E, I, 0 126.*, 182.210, 182.220, Nο 182.290, 182.3, 182.4*, 182.60*, 182.62*, 182.A1*, 182.B1*, 182.C1*, 182.890, 182.90 Medical record review Descriptive monitoring Monitoring period Setting ICD-10 codes Acute respiratory E, I J80 0-84 d No distress syndrome T78.2*, T80.52*, T88.6* Anaphylaxis 0-1 dE, I Yes, prespecified 0-84 d E, I MIS-C M35.81 Yes, prespecified^b 0-84 d Narcolepsy or cataplexy E, I, 0 G47.41* No

E, emergency department; I, inpatient; ICD-10, International Classification of Diseases, Tenth Revision, Clinical Modification; 0, outpatient; *, wildcard.

^a Additional information on outcome definitions, including exclusions and onset adjustments, is available at https://www.cdc.gov/vaccinesafety/pdf/COVID19-RCA-Protocol-1342-508.pdf or https://doi.org/10.1001/jama.2021.15072. All outcomes are the first since October 1, 2015 (the start of ICD-10 implementation within VSD) except myocarditis and pericarditis, which is first in 7 d

^b All electronically identified outcomes up to 84 d following COVID-19 vaccination were reviewed.