**Suspected Thrombosis & Thrombocytopenia following administration of COVID-19 vaccine\***

Local Identification Number: Adverse Event Reference Number:

Patient Initials: Patient Age: Patient Sex:

Ethnicity:

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| **Source of information** | | | |
| Name of the person reporting |  | Position (e.g. specialty and grade) |  |
| Hospital / Practice |  | Email address |  |

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| **Patient Background** | |
| Past Medical History: | |
| Regular and recent medications: | |
| Previous reactions to medications, especially heparin or anticoagulants | Yes/ No/ Unsure |
| Infectious illness in the last six weeks: | Yes/ No/ Unsure |
| Other vaccination received in the last six weeks: | Yes/ No/ Unsure |
| Previous adverse reaction to a vaccine: | Yes/ No/ Unsure |
| History of neurological disease (previous or current): | Yes/ No/ Unsure |
| Immunosuppression at the time of vaccination, including HIV: | Yes/ No/ Unsure |
| History of thromboembolic disease, including deep vein thrombosis, pulmonary embolism and cerebral venous sinus thrombosis | Yes/ No/ Unsure |
| Previous arterial thrombosis, including ischaemic stroke, myocardial infarction or acute coronary syndrome | Yes/ No/ Unsure |
| History of thrombocytopenia | Yes/ No/ Unsure |
| History of confirmed or suspected autoimmune or inflammatory disease, including vasculitis | Yes/ No/ Unsure |
| History of liver disease | Yes/ No/ Unsure |
| History of renal disease | Yes/ No/ Unsure |
| History of malignancy | Yes/ No/ Unsure |
| History of neurological/neurosurgical procedure, including lumbar puncture | Yes/ No/ Unsure |
| Obesity (BMI ≥30) | Yes/ No/ Unsure |
| Current smoker | Yes/ No/ Unsure |
| If Yes to any above, please provide details: | |

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| **Patient’s Covid-19 Status** | |
| Previous diagnosis of Covid-19: | Yes, once/  Yes, more than once/ No/ Unsure |
| If Yes, date of onset: | Date: |
| If Yes, means of diagnosis: | PCR/ Antibody / Clinical |
| If yes, severity of illness | Asymptomatic/ Symptoms self-managed/  Sought medical advice/ Admitted to hospital/  Required respirataory support in hospital |

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| **Vaccination Details** | |
| 1st vaccination: Pfizer-BioNTech/ Oxford- AstraZeneca/ Moderna/ Sinopharm/ Sinovac/ Sputnik V/ Other- specify:  Lot number: \_\_\_\_\_ Dose: \_\_\_\_ Route of administration: | Date: |
| 2nd vaccination: Pfizer-BioNTech/ Oxford- AstraZeneca/ Moderna/ Sinopharm/ Sinovac/ Sputnik V/ Other- specify:  Lot number: \_\_\_\_\_ Dose: \_\_\_\_ Route of administration: | Date: |
| Date of onset of symptoms relating to thrombosis or thrombocytopenia | Date: |

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| **Case Definition** | |
| Venous or arterial thrombosis  If Yes, Date of onset of clinical features: \_\_/\_\_/\_\_\_\_  Date of diagnosis: \_\_/\_\_/\_\_\_\_ | Yes/No/Unsure |
| Was there associated thrombocytopenia <150 × 109/L  If Yes, Date of onset of clinical features (if any): \_\_/\_\_/\_\_\_\_  Date of diagnosis: \_\_/\_\_/\_\_\_\_ | Yes/No/Unsure |
| PLUS Unknown Aetiology | Yes/No/Unsure |

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| **Clinical Features – Cerebral Venous Sinus Thrombosis** |
| Time from onset to peak symptoms: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Method of diagnosis: CT venogram/ MR venogram/ plain CT head/ plain MR head/ Other- specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Location: Right-sided/ Left-sided/ Bilateral |
| Specific location (select all that apply): Superior sagittal sinus/ Inferior sagittal sinus/ Lateral sinus/ Cavernous sinus/ Straight sinus/ Other- specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Headache: Yes/ No/ Unsure. If Yes, side: Right/ Left/ Bilateral |
| Seizures: Yes – generalised/ Yes – focal/ Yes – unclear type/ No |
| Limb weakness with upper motor neuron signs: Yes/ No/ Unsure  Affected limbs (select): RUL/ LUL/ RLL/ LLL |
| Sensory disturbance: Paraesthesia/Hypoesthesia/ No/ Unsure  Modality affected: Light touch/ Vibration/ Proprioception/ Pinprick/ Temperature  Please describe distribution: |
| Visual disturbance: Yes (select below)/ No/ Unsure  Reduced visual acuity/ RAPD/ Visual field defect- specify: \_\_\_\_\_\_\_\_\_/ Diplopia |
| Facial weakness: Yes - right/ Yes – left/ Yes – bilateral/ No/ Unsure  Dysphagia: Yes/ No/ Unsure  Dysphasia: Expressive/ Receptive/ Both/ No/ Unsure  Dysarthria: Yes/ No/ Unsure |
| Cerebellar signs: Yes/ No/ Unsure  Nystagmus/ Ataxia/ Intention tremor/ / Other- specify: |
| Other relevant symptoms and signs, including systemic features: |
| Has the patient experienced a similar event before? Yes/No/Unsure  If Yes, please provide details, including the date and suspected aetiology: |

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| **Clinical Features – Splanchnic Vein Thrombosis** |
| Time from onset to peak symptoms: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Method of diagnosis: Ultrasound/ CT scan/ Other- specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Abdominal pain: Yes/ No/ Unsure. If Yes, side: Right/ Left/ Bilateral |
| Portal vein/ Splenic vein/ Mesenteric vein/ Hepatic vein/ Other- specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Abdominal distension/swelling: Yes/ No/ Unsure |
| Vomiting: Yes/ No/ Unsure |
| Fever: Yes/ No/ Unsure |
| Splenomegaly: Yes/ No/ Unsure |
| Sepsis: Yes/ No/ Unsure Shock: Yes/ No/ Unsure |
| Gastrointestinal bleeding: Upper/ Lower/ None/ Unsure |
| Other relevant symptoms and signs, including systemic features: |
| Has the patient experienced a similar event before? Yes/No/Unsure  If Yes, please provide details, including the date and suspected aetiology: |

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| **Clinical Features – Pulmonary Embolism** |
| Time from onset to peak symptoms: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Method of diagnosis: CT pulmonary angiogram/ VQ scan/ Other- specify: \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Type: Subsegmental/ Segmental/ Lobar/ Saddle/ Unsure/ Other- specify: \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Breathlessness: Yes/ No/ Unsure |
| Chest pain: Yes/ No/ Unsure |
| Cardiac features: Sinus tachycardia/ Arrhythmia- specify: \_\_\_\_\_\_\_\_\_\_/ Right heart strain/ Other-specify: \_\_\_\_\_\_\_\_ |
| Hypotension: Yes/ No/ Unsure |
| Syncope/collapse: Yes/ No/ Unsure |
| Co-existing deep vein thrombosis: Yes/ No/ Unsure  If Yes, when diagnosed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Location: Upper limb(s)/ Lower limb(s) |
| Treatment: Anticoagulation alone/ Thrombolysis/ None- reason: \_\_\_\_\_\_\_\_\_\_/ Unsure/ Other- specify: \_\_\_\_\_\_\_\_\_\_\_\_ |
| Other relevant symptoms and signs, including systemic features: |
| Has the patient experienced a similar event before? Yes/ No/ Unsure  If Yes, please provide details, including the date and suspected aetiology: |

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| **Clinical Features – Arterial Thrombosis** |
| Location of thrombosis: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Time from onset to peak symptoms: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Method of diagnosis: Ultrasound/ CT scan/ Other- specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Relevant symptoms and signs, including systemic features: |
| Treatment: Anticoagulation alone/ Systemic Thrombolysis/ Local catheter-thrombolysis/ None- reason: \_\_\_\_\_\_\_\_\_\_/ Unsure/ Other- specify: \_\_\_\_\_\_\_\_\_\_\_\_ |
| Has the patient experienced a similar event before? Yes/No/Unsure  If Yes, please provide details, including the date and suspected aetiology: |

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| **Clinical Features & Laboratory Results – Thrombocytopenia** |
| **First** platelet count **after** vaccine: \_\_\_\_\_\_ × 109/L (usual normal range 150-450) Date: \_\_/\_\_/\_\_\_\_  Further details, e.g. remarks from laboratory, or reason if not available: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Lowest** platelet count **after** vaccine: \_\_\_\_\_ × 109/L (usual normal range 150-450) Date: \_\_/\_\_/\_\_\_\_  Further details, e.g. remarks from laboratory, or reason if not available: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Latest** platelet count **after** vaccine: \_\_\_\_\_\_ × 109/L (usual normal range 150-450) Date: \_\_/\_\_/\_\_\_\_  Further details, e.g. remarks from laboratory, or reason if not available: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Last** platelet count **before** vaccine if known: \_\_\_\_\_\_ × 109/L (usual normal range 150-450)  Date: \_\_/\_\_/\_\_\_\_  Not available/ further details: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Bleeding: Yes/ No/ Unsure  If Yes, location(s) and severity and need for treatment: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Bruising: Yes/ No/ Unsure. If Yes, location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Buccal haemorrhages: Yes/ No/ Unsure |
| Petechial rash: Yes/ No/ Unsure. If Yes, location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Fever: Yes/ No/ Unsure |
| Splenomegaly: Yes/ No/ Unsure |
| Review by haematologist: Yes/ No/ Unsure  If Yes, diagnosis or differential diagnoses: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Other relevant symptoms and signs, including systemic features: |
| Has the patient experienced thrombocytopenia before? Yes/No/Unsure  If Yes, please provide details, including the date and suspected aetiology: |

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| **Assessment and investigations to exclude other causes** (please indicate which of the following have been considered, and give details at the bottom) | |
| **Clinical assessment** | |
| History of thromboembolic disease – venous  History of arterial thrombotic disease  Atrial fibrillation  Other cardiac source of thrombus  Hypercoaguable state (e.g. sickle cell disease, pregnancy, coagulopathy, active inflammatory bowel disease)  Patient has had heparin in the last 2 weeks  On Combined Oral Contraceptive Pill | Yes/ No/ Unsure  Yes/ No/ Unsure  Yes/ No/ Unsure  Yes/ No/ Unsure  Yes/ No/ Unsure  Yes/ No/ Unsure  Yes/ No/ Unsure |
| **Laboratory studies** | |
| HbA1c  Lipid profile  Urea and Electrolytes  HIT assay – ELISA  HIT assay – functional e.g. AcuStar  ESR  Vasculitis screen\*  Homocysteine  Antithrombin deficiency  Protein S deficiency  Protein C deficiency  Lupus anticoagulant  Anti-β2 glycoprotein-1 antibody  Jak2 mutation or other MPN mutation  Factor V Leiden mutation  G20210 A prothrombin gene mutation  HIV serology  Quantiferon-TB or alternative  Syphilis serology  COVID-19 serology or PCR  PNH screen | Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Absent/ Unknown/ Not Done/ Present Absent/ Unknown/ Not Done/ Present  Absent/ Unknown/ Not Done/ Present Absent/ Unknown/ Not Done/ Present  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal |
| \*Please list tests comprising vasculitis and other thrombophilia screen: | |
| CSF Biochemistry**:** CSF Protein: \_\_\_\_\_\_\_ Serum: CSF Glucose Ratio: \_\_\_\_\_\_\_\_\_  CSF RCC: \_\_\_\_\_\_\_\_\_ CSF WCC: \_\_\_\_\_\_\_\_ CSF differential: \_\_\_\_\_\_\_\_\_ Date: \_\_/\_\_/\_\_\_\_ | |
| CSF Microscopy & culture  CSF Virology\*\* | Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal |
| \*\*Please list the pathogens tested with the CSF panels: | |
| Any other relevant laboratory results: | |
| **Radiological studies** | |
| CT  MRI  CT-Angiogram/ MR-Angiogram  Echocardiogram  US Doppler  Ultrasound - other | Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal  Normal/ Unknown/ Not Done/ Abnormal |
| **Details of any abnormal findings:** | |
| **Please describe if any of the findings could explain the aetiology of the event:** | |

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| **Treatment** (including dose and duration) |
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| **Patient outcome** |
| Date of last follow-up (if none, write none): |
| Maximum level of care required:  Outpatient/ Medical Inpatient/ High Dependency Unit/ Intensive Care Unit |
| Patient alive at last follow-up: Yes/ No  If No, was the thrombotic event or thrombocytopenia included on the death certificate: Yes/ No/ Unknown  If relevant, date of death: |
| Outcome at least follow up (circle): Complete resolution / Incomplete resolution / No improvement / Re-occurrence / Other sequalae  If relevant, time to complete resolution:\_\_\_\_\_\_\_\_\_\_ |
| Modified Rankin Scale: Before adverse event:\_\_\_\_\_\_\_ At the last follow-up: \_\_\_\_\_\_  *6 – Dead; 5 – Severe disability (requires constant nursing care and attention, bedridden, incontinent); 4 – Moderately severe disability (unable to walk without assistance and unable to attend to own bodily needs without assistance); 3 – Moderate disability (requires some help, but able to walk without assistance); 2 – Slight disability (unable to carry out all previous activities, but able to look after own affairs without assistance); 1 – No significant disability despite symptoms; 0 – No symptoms at all.* |
| Details: |

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| **Subsequent COVID-19 Vaccinations** | |
| Has this patient received any further COVID-19 vaccines after the development of the neurological adverse event? | Yes/ No/ Unsure |
| If Yes: Pfizer-BioNTech/ Oxford- AstraZeneca/ Moderna/ Sinopharm/ Sinovac/ Sputnik V/ Other- specify:  Lot number: \_\_\_\_\_ Dose: \_\_\_\_ Route of administration: | Date: |
| If Yes, Outcome: No adverse event/ Re-occurrence of the same adverse event/ Development of another neurological adverse event/ Worsening of previously unresolved neurological adverse event/ Other sequelae  Date the outcome was last known: | |
| Other details: | |