**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 thrombosisIf Yes, Date of onset of clinical features: \_\_/\_\_/\_\_\_\_ Date of diagnosis: \_\_/\_\_/\_\_\_\_ | Yes/No/Unsure |
| Was there associated thrombocytopenia <150 × 109/LIf 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/ UnsureAffected limbs (select): RUL/ LUL/ RLL/ LLL |
| Sensory disturbance: Paraesthesia/Hypoesthesia/ No/ UnsureModality affected: Light touch/ Vibration/ Proprioception/ Pinprick/ Temperature Please describe distribution: |
| Visual disturbance: Yes (select below)/ No/ UnsureReduced visual acuity/ RAPD/ Visual field defect- specify: \_\_\_\_\_\_\_\_\_/ Diplopia |
| Facial weakness: Yes - right/ Yes – left/ Yes – bilateral/ No/ UnsureDysphagia: Yes/ No/ UnsureDysphasia: Expressive/ Receptive/ Both/ No/ UnsureDysarthria: Yes/ No/ Unsure |
| Cerebellar signs: Yes/ No/ UnsureNystagmus/ Ataxia/ Intention tremor/ / Other- specify: |
| Other relevant symptoms and signs, including systemic features: |
| Has the patient experienced a similar event before? Yes/No/UnsureIf 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/UnsureIf 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/ UnsureIf 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/ UnsureIf 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/UnsureIf 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/ UnsureIf 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/ UnsureIf Yes, diagnosis or differential diagnoses: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Other relevant symptoms and signs, including systemic features: |
| Has the patient experienced thrombocytopenia before? Yes/No/UnsureIf 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 – venousHistory of arterial thrombotic diseaseAtrial fibrillationOther cardiac source of thrombusHypercoaguable state (e.g. sickle cell disease, pregnancy, coagulopathy, active inflammatory bowel disease)Patient has had heparin in the last 2 weeksOn Combined Oral Contraceptive Pill | Yes/ No/ UnsureYes/ No/ UnsureYes/ No/ UnsureYes/ No/ UnsureYes/ No/ UnsureYes/ No/ UnsureYes/ No/ Unsure |
| **Laboratory studies** |
| HbA1cLipid profileUrea and ElectrolytesHIT assay – ELISA HIT assay – functional e.g. AcuStarESRVasculitis screen\*HomocysteineAntithrombin deficiencyProtein S deficiencyProtein C deficiencyLupus anticoagulantAnti-β2 glycoprotein-1 antibodyJak2 mutation or other MPN mutationFactor V Leiden mutationG20210 A prothrombin gene mutationHIV serologyQuantiferon-TB or alternativeSyphilis serologyCOVID-19 serology or PCRPNH screen | Normal/ Unknown/ Not Done/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ 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/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ 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 & cultureCSF Virology\*\* | Normal/ Unknown/ Not Done/ AbnormalNormal/ 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-AngiogramEchocardiogramUS Doppler Ultrasound - other | Normal/ Unknown/ Not Done/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ Unknown/ Not Done/ AbnormalNormal/ 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/ NoIf No, was the thrombotic event or thrombocytopenia included on the death certificate: Yes/ No/ UnknownIf relevant, date of death: |
| Outcome at least follow up (circle): Complete resolution / Incomplete resolution / No improvement / Re-occurrence / Other sequalaeIf 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 sequelaeDate the outcome was last known: |
| Other details: |