

## Annex 1

### Updated (Aug 2021) COVID-19 AESI including status of associated Brighton case definitions

AESI <sup>Rationale to include as AESI (1, 2, 3, 4 and/or 5)</sup>	Brighton Case Definition Status
AESI included because they are seen with COVID-19 Disease <sup>3,4</sup>	
Acute respiratory distress syndrome	Published <sup>6</sup>
Multisystem inflammatory syndrome (children & adults)	Published <sup>6</sup>
1. Myocarditis / pericarditis 2. Other forms of acute cardiac injury including arrhythmias, heart failure, coronary artery disease, myocardial infarction, stress cardiomyopathy	1.Completed, submitted to Vaccine <sup>6</sup> 2.No Brighton case definition to be developed but companion guide to myocarditis/pericarditis will include background rates and ICD/MedDRA codes
Coagulation disorder (includes thrombotic disorders, bleeding disorders)	Thrombosis near completion. Bleeding disorder WG to be formed
Anosmia, ageusia	WG formed & developing case definition
Chilblain – like lesions	WG to be formed
Erythema multiforme	Not yet started
Single Organ Cutaneous Vasculitis	Published
Acute kidney injury	Published lab-based criteria (see *)
Acute liver injury	Published lab-based criteria (see #)
Acute pancreatitis	Not yet started
Rhabdomyolysis	Not yet started
Subacute thyroiditis	Not yet started
AESI included because they have a proven or theoretical association with immunization in general	
Anaphylaxis <sup>1,2</sup>	Published <sup>6</sup>
Thrombocytopenia <sup>1,2,3,4</sup>	Published <sup>6</sup>
Generalized convulsion <sup>1,2</sup>	Published <sup>6</sup>
Acute disseminated encephalomyelitis <sup>4</sup>	Published <sup>6</sup>
Guillain Barré Syndrome <sup>3,4</sup>	Published <sup>6</sup>
AESI included because they have a proven or theoretical association with specific vaccine platform(s)	
Acute aseptic arthritis <sup>r-VSV</sup>	Published <sup>6</sup>
Aseptic meningitis <sup>Live vaccines</sup>	Published <sup>6</sup>
Encephalitis / Encephalomyelitis <sup>Live vaccines</sup>	Published <sup>6</sup>
Bell's Palsy <sup>Intranasal EColi Heat Labile Toxin Adjuvanted Vaccine</sup>	Published <sup>6</sup>
Vaccine associated enhanced disease <sup>1(Formalin inactivated measles/RSV; HIV), 2(Chimeric YF Dengue), 5 (SARS / MERS-CoVs)</sup>	Published <sup>6</sup>

<sup>1</sup> Proven association with immunization encompassing several different vaccines

<sup>2</sup> Proven association with vaccine that could theoretically be true for novel COVID-19 vaccines

<sup>3</sup> Theoretical concern based on wild type disease immunopathogenesis

<sup>4</sup> Theoretical concern related to viral replication during wild type disease

<sup>5</sup> Theoretical concern because it has been demonstrated in an animal model with ≥ 1 vaccine platform

\* Acute kidney injury—consensus definition of Kidney Disease Improving Global Outcomes expert consensus group [www.kdigo.org](http://www.kdigo.org)

• Increase in serum creatinine by ≥ 0.3 mg/dl (≥26.5 umol/l) within 48 hours; OR

- Increase in serum creatinine to  $\geq 1.5$  times baseline, known or presumed to have occurred within prior 7 days OR
  - Urine volume  $\leq 0.5$  ml/ kg/ hour for 6 hours
- # Acute liver injury – definition as used in majority of COVID-19 publications (but no international consensus):
- > 3-fold elevation above the upper normal limit for ALT or AST OR
  - > 2-fold elevation above the upper normal limit for total serum bilirubin or GGT or ALP

<sup>6</sup>Case Definition and resources available at:  
[https://docs.google.com/spreadsheets/d/1QgF35nYcsaFN3DZT0tV\\_IP0TYqQzsDMUQBAd5M9brM/edit#gid=1666959512](https://docs.google.com/spreadsheets/d/1QgF35nYcsaFN3DZT0tV_IP0TYqQzsDMUQBAd5M9brM/edit#gid=1666959512)