

# Reporting Potential Adverse Reactions or Events Following COVID Vaccination

VUMC clinicians may be asked to assess a clinical syndrome/event that has occurred temporally following a COVID vaccination. These events may not clearly be due to the COVID vaccination, but clinicians who suspect a possible relationship to COVID vaccination are requested to report such events as part of the Centers for Disease Control and Prevention's (CDC) Vaccine Adverse Event Reporting System (VAERS) process for post-authorization safety event surveillance. The process for reporting these events is outlined below:

- 1) **For any events or symptoms that develop after COVID vaccination and may, in the determination of the evaluating clinician, be related to receipt of the COVID vaccine:**
  - Use the eStar COVID Vaccine Reporting Flowsheet to provide added detail to the event. Additional details on the use of this tool may be found here ([eStar Tip Sheet](#)).
  - Centralized reporting of the event to the CDC VAERS will then occur; the clinician does not need to do anything further unless the event meets the criteria for severe post-vaccination event noted in 2) below.
- 2) **For specific events deemed by the Federal Drug Agency (FDA) as severe (see list below) and required as part of the vaccine authorization requirements,** report these as defined in #1 above AND submit a separate VERITAS report through the usual process.

## Mandatory Post-Vaccination Reporting Events (FDA):

- Serious adverse events defined as “death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, a congenital anomaly/birth defect, an important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above”
- Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children,
- Cases of COVID-19 that result in hospitalization or death.