

COVID-19 Vaccine Adverse Events: How to Report

Significant adverse events and reactions to COVID-19 vaccines *must* be reported to:

CARS

(Clinical Advice and Response Service)

Please email CARS via

england.swcovid19-voc@nhs.net

The following guidelines should be followed when deciding what to report:

- ♦ Any side-effect/reaction that is not already noted in the manufacturer's SPC and that the clinician considers to be possibly linked chronologically to the vaccination.
- ♦ A known side-effect/reaction noted on the SPC but that the clinician considers to be an extreme form of this known side-effect, e.g., fever that lasts more than expected number of days, and for which there is no other cause, an urticarial reaction that affects a much larger area than just at the injection site etc.
- ♦ An acute clinical event, hospitalization or death linked in time to the vaccination for which the clinician does not consider there to be any other clinical cause.

IF IN DOUBT, REPORT IT

Following initial investigation and if appropriate, you may be directed by CARS to complete the following online forms:

Allergic Reactions and Other Serious immediate Adverse Events e.g. cardiac arrest, death, hospitalisation, etc

(event within 72 hours of vaccination)

(<https://cutt.ly/covid-ae>)

Yellow card reports

Please note, you should still report to the MHRA Yellow card system:

<https://coronavirus-yellowcard.mhra.gov.uk/>

Note: you can use the information inputted into the first online form to generate a core text which you can then cut and paste into the Yellow Card form, Datix or any other regional systems to avoid duplication of work.