

Issue 75 - COVID-19 vaccine safety report – 23 September 2022 ([D22-5897399](#))

Myocarditis/pericarditis	<ul style="list-style-type: none"> • s22 to update myo and peri ADRs and vaccine doses.
Other topics	<ul style="list-style-type: none"> • VSIG outcomes D22-5869669 (sent to VSIG comms experts for review)
PI updates	<ul style="list-style-type: none"> • s22 PI – acute disseminated encephalomyelitis as a warning in section 4.4 and cutaneous vasculitis as an AE in section 4.8 <p>In progress:</p> <ul style="list-style-type: none"> • Menstrual disorders and vaccination – MAVIS doing another TIP • MAVIS looking into vulvovaginal ulceration after a few reports from WHO. (FDA investigated and found no signal)
MAVIS investigations	

COVID-19 Vaccine International Regulator Updates

Regulatory agency	What's new
Health Canada To 2 Sep 2022 s22 s22	Nothing new - next report due on 3 Oct
MHRA United Kingdom To 1 Sep 2022 s22	Nothing new - monthly publication
US CDC, MMWR To 12 Sep 2022 s22 preferred over s22	Report is fortnightly.
Norway 1 April 2022 s22	Reports now only published in Norwegian.
Swiss Medic 26 August 2022 s22	Nothing new - report here
HSA Singapore 27 June 2022. s22	Nothing new
EMA-PRAC	Nothing new on COVID-19 vaccines since 4-7 July
WHO	Nothing on vaccine safety. Interim statement on COVID-19 vaccination for children – 11 August