

Table1. Vaccines and their pregnancy specific post-marketing studies. Vaccine developers have shown commitment to conduct post-marketing safety and active surveillance studies and registries in pregnant women. Pfizer/BioNTech, AstraZeneca/the University of Oxford and Moderna have published their proposed specific post-marketing studies while other developers such as Johnson & Johnson/ Janssen Pharma and Novavax are in late-stage clinical trials.

Developer	Vaccine Name and Component	Current Stage	Eligibility criteria for pregnant women Phase 1-3	Pregnancy specific post-marketing studies
Pfizer and BioNTech	BNT162b2 (mRNA of Full length spike protein in a lipid nanoparticle)	Post-marketing	Pregnant/ breastfeeding Excluded	<p>C4591001:* A Phase 1/2/3, placebo controlled, randomised, observer-blind, dose finding study to evaluate the safety, tolerability, immunogenicity, and efficacy of SARS-COV-2 RNA vaccine candidates against COVID-19 in healthy individuals</p> <p>C4591015: A Phase 2/3, Placebo- Controlled, Randomised, Observer-Blinded Study to Evaluate the Safety, Tolerability, and Immunogenicity of a SARS-CoV-2 RNA Vaccine Candidate (BNT162b2) Against COVID-19 in Healthy Pregnant Women 18 Years of Age and Older</p> <p>C4591008: Post-Emergency Use Authorization Observational Cohort Study to evaluate the safety of SARS-COV-2 RNA Vaccine in Healthcare Workers: A primary data collection active surveillance study</p> <p>C4591011: Safety Surveillance of the Pfizer COVID-19 Vaccine in the U.S. Department of Defence Population Following Emergency Use Authorization</p> <p>C4591012: Post-Emergency Use Authorization Active Surveillance of Adverse Events of Special Interest among Individuals in the Veteran's Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine</p>
AstraZeneca and the University of Oxford	AZD1222 ChAdOx1 nCoV-19 (replication deficient adenovirus type 5 vector expressing full length	Post-marketing	Pregnant/ breastfeeding Excluded	<p>D8111R00003, D8111R00004*: Enhanced active surveillance A Phase IV Enhanced Active Surveillance Study of People Vaccinated with AZD1222</p> <p>No study code: AZD1222 Pregnancy Registry of Women Exposed to AZD1222 Immediately Before or During Pregnancy</p>

	spike protein)			
Moderna	mRNA-1273 (mRNA of full-length spike protein in a lipid nanoparticle)	Post-marketing	Pregnant/ breastfeeding Excluded	NCT04470427* : Sponsor has committed to a 3-year passive pregnancy registry. A US based prospective observational study may take place
Johnson & Johnson/ Janssen Pharma	Ad26.COVS.2 or JNJ-78436735 (replication deficient Adenovirus type 26 vector expressing full length spike protein)	Phase 3 trial in progress, interim results expected Q1 2021	Lactating women are permitted in Phase 3 study Pregnant women excluded but Ad26+ has had exposure in Ebola (1000 patients)	Details awaited
Novavax	NVX-CoV2373 (a “nanoparticle” of trimeric full length recombinant spike protein formulated in Matrix-M1 adjuvant)	Phase 3 trial ongoing, interim data expected Q1 2021	Pregnant/ breastfeeding Excluded	Details awaited

* Ongoing Phase 4 studies of original phase1/2/3 subjects. Surveillance is planned on average for 2 years following dose 2. The sponsors will release details of all details of all inadvertent pregnancies which occurred prior in pre-marketing clinical studies on a periodic basis to regulators.