



## **Statement from IVFMD regarding mRNA COVID-19 vaccines**

As of 1/1/21, two pharmaceutical companies have provided vaccines for release under Emergency Use Authorization authority (EUA). According to the U.S. Food and Drug Administration (FDA): “During a public health emergency, the FDA can use its Emergency Use Authorization (EUA) authority to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives. Before the FDA can issue an EUA, the Secretary of Health and Human Services must make a declaration of emergency or threat justifying authorization of emergency use for a product.”

Within the Pfizer “fact sheet for healthcare providers administering vaccine” (<https://www.fda.gov/media/144413/download>), the word “**FERTILITY**” does not appear.

The section on **PREGNANCY** states:

“All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.”

Within the Moderna “fact sheet for healthcare providers administering vaccine” (<https://www.fda.gov/media/144637/download>), the word “**FERTILITY**” appears once:

“Moderna COVID-19 Vaccine was administered to female rats by the intramuscular route on four occasions: 28 and 14 days prior to mating, and on gestation days 1 and 13. No vaccine-related adverse effects on female fertility, fetal development or postnatal development were reported in the study.”

The section on **PREGNANCY** states:

“There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866-663-3762).

### Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available data on Moderna COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine associated risks in pregnancy.

Official statements from The American College of Obstetricians & Gynecologists (ACOG) and The American Society for Reproductive Medicine (ASRM) state, respectively:

“ACOG recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups.”



“The (ASRM) Task Force does not recommend withholding the vaccine from patients who are planning to conceive, who are currently pregnant, or who are lactating”.

After reading the above information, you should make an informed decision regarding risks vs. benefits and determine if the COVID-19 vaccination is right for you.

*As new information becomes available, IVFMD will strive to update the information contained herein. Be sure to check back frequently.*