

Recommended Biomedical CDEs: Post-Acute Sequelae of SARS-CoV-2 in Pregnancy and Postpartum

A subset of measures included here are designated as “Tier 2.” Those without this designation—i.e., “Tier 1” measures—are recommended for all studies that may include participants of reproductive age and pregnant individuals. Tier 2 measures are suggested additional measures for studies focused exclusively on COVID-19 in pregnancy and/or for any study interested in taking a “deeper dive” in certain domains.

COVID-19 Vaccination History

- Have [you/the participant] received a vaccination for COVID-19?
 - No (*If no, skip to...“if not vaccinated, why?”*)
 - Yes

- Have [you/the participant] completed the vaccination for COVID-19 (dose or doses)?
 - No (*If no, skip to...“if not vaccinated, why?”*)
 - Yes
 - **If yes**, on what date did the patient receive the first dose of vaccine?
 - Month/Day/Year
 - **If yes**, on what date did the patient receive the second dose of vaccine?
 - Month/Day/Year
 - N/A
 - Enter the name of the vaccine (if known)?¹
 - AstraZeneca’s COVID-19 vaccine
 - Janssen’s (Johnson & Johnson) COVID-19 vaccine
 - Moderna’s COVID-19 vaccine
 - Novavax’s COVID-19 vaccine
 - Pfizer’s COVID-19 vaccine
 - Other, Specify
 - [Tier 2] Did [you/the participant] receive a COVID-19 vaccine 90 days after treatment with monoclonal antibodies or 30 days after an active COVID-19 infection?
 - No
 - Yes
 - Unknown
 - Prefer not to answer

- Did you experience any side effects within 2 weeks after the **FIRST** vaccine dose?²
 - No
 - Yes
 - I do not know
 - If yes, what side effect(s) did you experience? Select all that apply.
 - Pain where shot was given
 - Fever ≥ 100.4 F
 - Fatigue/tiredness
 - Headache
 - Muscle pain in parts of your body beyond where shot was given

¹ Project 5 Draft CDEs/FDA

² DR2 Vaccine Questions

- Immediate, severe allergic reaction (including difficulty breathing and feeling faint, nausea and/or vomiting)
 - Skin rash
 - Facial swelling
 - Other (please describe)
- Did you experience any side effects within 2 weeks after the **SECOND** vaccine dose [if applicable]?
 - No
 - Yes
 - I do not know
- If yes, what side effect(s) did you experience? Select all that apply.
 - Pain where shot was given
 - Fever ≥ 100.4 F
 - Fatigue/tiredness
 - Headache
 - Muscle pain in parts of your body beyond where shot was given
 - Immediate, severe allergic reaction (including difficulty breathing and feeling faint, nausea and/or vomiting)
 - Skin rash
 - Facial swelling
 - Other (please describe)
- [Tier 2] Medications to treat symptoms post-vaccine
 - Ibuprofen
 - Acetaminophen
 - Aspirin
 - Antihistamines
 - Other, specify: _____
- If not vaccinated, Why? (Select ONE best reason)
 - The vaccine is not available to me
 - Doctor did not recommend it
 - My family did not want me to take it
 - It was not well tested in ethnically diverse people
 - It was not well tested among pregnant individuals
 - I cannot afford the vaccine
 - I have not had time to get it
 - I'm at low risk and do not need it
 - It is riskier to go get the vaccine than staying at home
 - Worried about side effects
 - The vaccine's technology hasn't been tested enough
 - Vaccine was approved too fast
 - No long-term safety data available
 - Concerned about vaccine storage
 - Already had COVID-19
 - Other, specify: _____

- Do you intend to receive a coronavirus (COVID-19) vaccine?³
 - I intend to get it as soon as possible
 - I intend to wait to see how it affects others in the community before I get it
 - I do not intend on getting it soon, but might sometime in the future
 - I do not intend to ever get the vaccine

- [Tier 2] Is there anything that might convince you to change your mind about getting vaccinated? (Based on those who would definitely not get the COVID-19 vaccine)⁴
 - No/Nothing
 - More research
 - If it were mandatory/required
 - Other
 - Don't know

³ DR2 Vaccine Questions

⁴ [Kaiser Family Foundation COVID-19 Vaccine Monitor April 2021](#)

⁵ [Vaccination Attitudes Examination \(VAX\) Scale](#)