

Pre-Registration Screening Questionnaire

Q#	Screening Question	Action To Be Taken
1.	<p>Have you ever had a severe life-threatening allergic reaction* (like anaphylaxis) to a prior dose of the Pfizer-BioNTech COVID-19 vaccine, or to any ingredients in the vaccine (which includes polyethylene glycol)?</p> <p>OR</p> <p>Have you ever had an allergic reaction of any severity within 4 hours after receiving a prior dose of the Pfizer-BioNTech COVID-19 vaccine or a diagnosed allergy to a specific ingredient in the vaccine (including polyethylene glycol)? <i>(Note: Allergic reactions can include symptoms such as hives; swelling of the face, mouth, or throat; or wheezing and difficulty breathing.)</i></p> <p>Ingredients in the Pfizer-BioNTech Vaccine include:</p> <ul style="list-style-type: none"> • Messenger RNA (mRNA) • Lipids: <ul style="list-style-type: none"> ○ ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) ○ 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide ○ 1,2-distearoyl-sn-glycero-3-phosphocholine ○ Cholesterol • Potassium chloride • Monobasic potassium phosphate • Sodium chloride • Dibasic sodium phosphate dihydrate • Sucrose 	
	➤ YES	Do NOT give the Pfizer-BioNTech or Moderna vaccine. Person may be given the Janssen vaccine if no contraindication to that vaccine (see Question 3 below), but person <u>must</u> discuss their allergy history with their primary care provider first and have a clinical assessment performed. Janssen vaccine must be scheduled to be given at least 28 days after any previous Pfizer vaccine dose (if applicable).
	➤ NO	Proceed to next question
2.	<p>Have you ever had a severe life-threatening allergic reaction* (like anaphylaxis) to a prior dose of the Moderna COVID-19 vaccine, or to any ingredient in the vaccine (which includes polyethylene glycol)?</p> <p>OR</p> <p>Have you ever had an allergic reaction of any severity within 4 hours after receiving a prior dose of the Moderna COVID-19 vaccine or a diagnosed allergy to a specific ingredient in the vaccine (including polyethylene glycol)? <i>(Note: Allergic reactions can include symptoms such as hives; swelling of the face, mouth, or throat; or wheezing and difficulty breathing.)</i></p> <p>Ingredients in the Moderna Vaccine include:</p> <ul style="list-style-type: none"> • Messenger RNA (mRNA) • Lipids: <ul style="list-style-type: none"> ○ SM-102 (proprietary to Moderna) ○ Polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG] ○ 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC] ○ Cholesterol • Tromethamine • Tromethamine hydrochloride • Acetic acid • Sodium acetate 	

	<ul style="list-style-type: none"> Sucrose 	
	<p>➤ YES</p>	<p>Do NOT give the Moderna or Pfizer-BioNTech vaccine. Person may be given the Janssen vaccine if no contraindication to that vaccine (see Question 3 below), but person <u>must</u> discuss their allergy history with their primary care provider first and have a clinical assessment performed. Janssen vaccine must be scheduled to be given at least 28 days after any previous Moderna vaccine dose (if applicable).</p>
	<p>➤ NO</p>	<p>Proceed to next question</p>
3.	<p>Have you ever had a <u>severe life-threatening allergic reaction*</u> (like anaphylaxis) to a prior dose of the Janssen COVID-19 vaccine, or any ingredients in the vaccine (which includes polysorbate)?</p> <p>OR</p> <p>Have you ever had an <u>allergic reaction of any severity</u> within 4 hours after receiving a prior dose of the Janssen COVID-19 vaccine or a <u>diagnosed allergy</u> to a specific ingredient in the vaccine (including polysorbate)? (<i>Note: Allergic reactions can include symptoms such as hives; swelling of the face, mouth, or throat; or wheezing and difficulty breathing.</i>)</p> <p>Ingredients in the Janssen Vaccine include:</p> <ul style="list-style-type: none"> Inactivated adenovirus particles Citric acid monohydrate Trisodium citrate dihydrate Ethanol 2-hydroxypropyl-β-cyclodextrin (HBCD) Polysorbate-80 Sodium chloride 	
	<p>➤ YES</p>	<p>Do NOT give Janssen vaccine. Person may be given either the Pfizer or Moderna vaccines if no contraindication to those vaccines (see Questions 1 & 2), but person must discuss their allergy history with their primary care provider first and have a clinical assessment performed.</p>
	<p>➤ NO</p>	<p>Proceed to next question</p>
4.	<p>Within the last 180 days, have you experienced or recovered from an immune condition that caused both blood clotting and low platelet cell counts to occur? (one example of this is a condition called “heparin-induced thrombocytopenia”, or HIT)</p>	
	<p>➤ YES</p>	<p>Do NOT give Janssen vaccine until at least 180 days have passed after a person recovers from an immune-mediated syndrome that caused both blood clotting and low platelet counts. Person may be given either the Pfizer or Moderna vaccines if no contraindication to those vaccines.</p>
	<p>➤ No</p>	<p>Proceed to next question</p>
5.	<p>Have you ever had a <u>severe life-threatening allergic reaction*</u> (like anaphylaxis) to anything (including other medications, food, substances, environmental exposures, etc.)?</p> <p>OR</p> <p>Have you ever had an <u>allergic reaction of any severity</u> within 4 hours after receiving another vaccine or injectable medication therapy (including medication injections into a vein, muscle, or under the skin)?</p>	

	➤ YES	Person can schedule vaccination, but recommend person first discuss their allergy history, and potential risks and benefits of the vaccine with their primary care provider. Provide person with <i>“Information about the COVID-19 Vaccine for Persons with Certain Health Conditions”</i> . When they receive the vaccine, they will be observed for 30 minutes after vaccination.
	➤ NO	Proceed to next question
6.	Have you received a passive antibody therapy to treat COVID-19 in the previous 90 days (this includes convalescent plasma and monoclonal antibodies, such as bamlanivimab and casirivimab/imdevimab)? (Note: COVID-19 vaccines should not be given for at least 90 days after a person received a passive antibody therapy as treatment of COVID-19 to avoid the possibility of the antibody therapy interfering with the vaccine.)	
	➤ YES	Do NOT schedule vaccination until 90 days have passed from time of passive antibody therapy.
	➤ NO	Proceed to next question
7.	Have you received another un-related vaccine (e.g., influenza) in the previous 14 days? (Note: the COVID-19 vaccine should be given alone and at least 14 days separate from other vaccines.)	
	➤ If Yes, what was the date of your last vaccination with another vaccine? (Enter Date)	
	➤ YES	Do NOT schedule vaccination until 14 days have passed from time of other vaccination(s).
	➤ NO	Proceed to next question
8.	Are you severely immunocompromised** (is your immune system weakened and not working properly)?	
	➤ YES	Person can schedule vaccination, but recommend person first discusses immunosuppressive condition, and potential risks and benefits of the vaccine with the provider managing their condition. Provide person with <i>“Information about the COVID-19 Vaccine for Persons with Certain Health Conditions”</i> .
	➤ NO	Proceed to next question
9.	Are you currently pregnant?	
	➤ YES	Person can schedule vaccination, but recommend person first discuss pregnancy, and potential risks and benefits of the vaccine with their obstetrics provider. Provide person with <i>“Information about the COVID-19 Vaccine for Persons with Certain Health Conditions”</i> .
	➤ NO	End

* Severe life-threatening allergic reactions include symptoms of anaphylaxis such as swelling of your face, mouth, or throat; wheezing or difficulty breathing; sudden loss of blood pressure, etc. usually requiring a person be given epinephrine and go to the hospital.

** Severely immunocompromised conditions include being on chemotherapy for cancer, being within one year out from receiving a hematopoietic stem cell or solid organ transplant, untreated HIV infection with a CD4 lymphocyte count of less than 200, primary immunodeficiency disorder, high levels of steroids, etc.