FOR HEALTHCARE PROFESSIONALS

[redacted] Trial Talking Points

About the [redacted] Trial

The [redacted] Trial is a [redacted] trial to evaluate [redacted] candidate seasonal flu vaccines in healthy adults.

Trial Purpose

The [redacted] Trial is evaluating the safety of three mRNA seasonal influenza (flu) vaccines, as well as the immune response and reactions in participants.

Trial Design

The [redacted] Trial is enrolling approximately 560 healthy adults. These participants will be randomized to receive one of the following: 1 dose of [redacted], 1 of 3 doses of [redacted] 1 of 3 doses of [redacted] or a commercially available flu vaccine. Each participant will receive 1 injection on Day 1.

The total length of participation is approximately 7 months. While enrolled in the trial, participants will need to attend at least 6 visits (including the screening visit) in person and 4 phone calls, as well as complete electronic diary (eDiary) entries on Day 1 after receiving the assigned investigational vaccine and for 6 days following the injection.

About the Investigational Vaccines

The vaccines being tested in this trial are called [redacted], [redacted], and [redacted]. The investigational vaccines are not made from a weakened or killed virus. Instead, they include a part of the messenger ribonucleic acid (mRNA) of the virus, and this man-made mRNA is thought to elicit antibodies that could potentially fight the virus. The investigational vaccine breaks down naturally and does not stay in the body. This is the first time that [redacted] and [redacted] are being tested; however, several other studies testing similar mRNA vaccines are also in progress.

[redacted]

Key Inclusion Criteria

- Adults 18 to 75 years of age at the time of consent (screening visit). Participants may be rescreened if they are not medically stable at the screening visit.
- Female participants of childbearing potential may be enrolled in the trial if the participant fulfills all the following criteria:
  - Has a negative pregnancy test at the screening visit and on the day of vaccination (Day 1).
  - Has practiced adequate contraception or has abstained from all activities that could result in pregnancy for at least 28 days prior to Day 1. Adequate female contraception is defined as consistent and correct use of a Food and Drug Administration (FDA)–approved contraceptive method in accordance with the product label.
  - Has agreed to continue adequate contraception through 90 days following vaccine administration.
  - Is not currently breastfeeding.
- Investigator assessment that participant understands and is willing and physically able to comply with protocol-mandated follow-up, including all procedures.

Key Exclusion Criteria

- Participant has had close contact to someone with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, or coronavirus disease 2019 (COVID-19) as defined by the CDC or has had a positive SARS-CoV-2 test in the past 10 days prior to the screening visit.
- History of myocarditis, pericarditis, or myopericarditis.
- Reported history of congenital or acquired immunodeficiency, immunosuppressive condition, or immune-mediated disease.
- Reported history of anaphylaxis or severe hypersensitivity reaction after receipt of any components of mRNA- or cell-based influenza (e.g., Flublok) vaccine.
- Participant has received a Northern Hemisphere 2021–2022 seasonal influenza vaccine or any other influenza vaccine within 180 days prior to Day 1.
- Participant has tested positive for influenza by CDC-recommended testing methods within 180 days prior to Day 1.

Refer a Patient

If you have a patient you feel may be eligible for the [redacted] Trial, and you think they may be interested in participation, please contact the trial site listed here.

Thank you for your consideration of the [redacted] Trial.

[redacted]

[redacted]

[redacted]