JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health
415 N. Washington Street, 2nd Floor
Baltimore, Maryland 21231

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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: The Moderna phase 3 COVID vaccine trial

With talk of having a vaccine by election, it is useful to look at the Moderna vaccine trial as registered on CT.gov. The estimated completion date is 27 October 2022, about the time of midterm elections.

The Moderna phase 3 COVID-19 vaccine trial
(information from NCT registry; 6 Sep 2020)

Registration number
NCT04470427

Name
A Study to Evaluate Efficacy, Safety, and Immunogenicity of mRNA-1273 Vaccine in Adults Aged 18 Years and Older to Prevent COVID-19

Official name
A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older

Sponsors; collaborators
ModernaTX, Inc; Biomedical Advanced Research and Development Authority; National Institute of Allergy and Infectious Diseases (NIAID)

Start date (start of enrollment)
27 July 2020

Estimated completion date
27 October 2022

Sample size planned
30,000

Primary outcome
Number of participants with first occurrence of COVID-19 starting 14 days after second dose of mRNA-1273

Period of followup
Up to 2 years after the second dose of mRNA-1273

Design
Randomized, double-masked, placebo-controlled

Study sites
99; all U.S. (7 not yet recruiting)

Eligibility

- Persons at high risk of SARS-CoV-2 infection
- Understands and agrees to comply with the study procedures and provides written informed consent
- Able to comply with study procedures based on the assessment of the Investigator
- Females of non-childbearing potential
- Females childbearing potential provided: Negative pregnancy test at Screening and on the day of the first dose; practiced contraception or abstained from activities that could result in pregnancy at least 28 days prior to the first dose; agreed to contraception through 3 months following the second dose on Day 29; not currently breast-feeding
- Healthy adults or adults with pre-existing medical conditions in stable condition

Exclusions

- Ill or febrile 72 hours prior to or at Screening
- Pregnant or breast-feeding.
- History of SARS-CoV-2 infection.
- Prior administration of an investigational coronavirus vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19
- Inability to comply with study procedures
- Family or household member of study personnel.
- History of anaphylaxis, urticaria, or other adverse reaction requiring medical intervention after receipt of a vaccine
- Bleeding disorder considered contraindication to intramuscular injection or phlebotomy
- Plans to receive a vaccine within 28 days prior to the first dose or plans to receive a non-study vaccine within 28 days prior to or after any dose of investigational product (except for seasonal influenza vaccine)
- Has participated in an interventional clinical study within 28 days prior to the day of enrollment
- Immunosuppressive or immunodeficient state
- Received systemic immunosuppressants or immune-modifying drugs for >14 days within 6 months prior to screening
- Has received systemic immunoglobulins or blood products within 3 months prior to the day of Screening
- Donated =450 milliliters (mL) of blood products within 28 days prior to screening