

# National Institutes of Health Update

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National Institute of  
Allergy and  
Infectious Diseases

# FluMos-v1: Universal Influenza Vaccine Candidate

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A computer-generated image showing HA epitopes arrayed on a nanoparticle  
*Credit: NIAID*







- NIH launches Phase 1 Clinical Trial of FluMos-v1
  - FluMos-v1 is an investigational nanoparticle influenza vaccine designed to provide long-lasting protection against multiple flu virus strains that was developed by NIAID scientists and collaborators at the University of Washington
  - **Purpose:** To assess the safety and immunogenicity of FluMos-v1
  - **Participants:** Up to 35 participants between 18 and 50 years old
  - **Location:** NIH Clinical Center, Bethesda, MD

# Research to Address Vaccine Hesitancy, Uptake, and Implementation among Populations that Experience Health Disparities

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- Notice of Special Interest (NOSI)
  - **Purpose:** To solicit community-engaged research to:
    - 1) Evaluate intervention strategies (e.g., expand reach, access) to facilitate vaccination uptake in clinical and community contexts; and
    - 2) Address the barriers to increasing reach, access, and uptake of vaccinations among health disparity populations at high risk and likely to experience vaccine hesitancy.
  - **Awards:** For example, National Institute on Minority Health and Health Disparities (NIHMD) recently awarded 5 research grants totaling \$14.5 million over 5 years for these grants, subject to available funds.  
<https://nimhd.nih.gov/news-events/news-releases/2021/pr-2021-06-04-vaccine-hesitancy-research.html>

# Overview of CoVID-19 Vaccine Candidates

Company	Platform	Product	Dose, schedule	Status
	mRNA	2P-stabilized Spike, TM, FI	2 doses (0, 28)	EUA issued; BLA submission 6/1/21; adolescent data (ages 12-17) submitted to FDA in June; enrolling ages 6mths-11yrs
	mRNA	Stabilized SARS-CoV-2 Spike	2 doses (0, 21)	EUA issued and expanded to adolescents (12-15yrs); BLA submission 5/7/21; enrolling ages 6mths-11yrs
	Ad Vector	ChAdOx1 wild type Spike; ΔF; TM <b>Ratio 2:1 Vaccine: Placebo</b>	2 doses (0, 28)	Ph3 fully enrolled
	Ad Vector	Ad26; stabilized Spike; ΔF; TM	1 dose	EUA issued
	Recombinant protein	Stabilized trimer Spike, ΔF; TM; Matrix M Adjuvant <b>Ratio 2:1 Vaccine: Placebo</b>	2 doses (0, 21)	Ph3 cross-over vacc placebo recip ongoing; adolescent expansion underway (ages 12-17)
	Recombinant protein	Stabilized Trimer Spike, ΔF; TM AS03 Adjuvant	2 doses (0, 21)	Phase 3 trial began 5/27/21; 2-stage design with initial stage testing adjuvanted monovalent; stage 2 adjuvanted bivalent for B.351 variant

# Pediatric COVID-19 Vaccines

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May 10, 2021

**The Washington Post**

***FDA authorizes Pfizer  
coronavirus vaccine for  
adolescents 12 to 15  
years old***

Carolyn Y. Johnson

June 10, 2021



**Moderna seeks FDA  
authorization for Covid-19  
vaccine for people  
ages 12 to 17**

Ben Tinker and Virginia Langmaid

# SNIFF Study

- Novavax is conducting a pediatric expansion of its Phase 3 clinical trial for NVX-CoV2373, the company's recombinant protein vaccine candidate against COVID-19.
  - Enrolling up to 3,000 adolescents aged 12-17 across up to 75 sites, including 8 CoVPN sites.
- Ancillary nasal swab study called SNIFF (**S**wab your **N**ose to **F**ind in**F**ection) to assess asymptomatic viral shedding of SARS-CoV-2.
  - First volunteers enrolled on June 1.



# COVID-19 Vaccines and Pregnancy

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## COVID Vaccines in Pregnancy Boost Maternal and Newborn Immunity, NIH-funded Study Suggests

- Enrolled 131 women of reproductive age to study vaccine response to Pfizer/BioNTech and Moderna vaccines in pregnancy.
- Vaccines generated strong immunity to COVID-19 in pregnant/breast-feeding women.
- Antibodies produced after vaccination are present in breastmilk and travel across the placenta, indicating that vaccination during pregnancy also confers immunity to newborns.

Gray KJ, et al. COVID-19 vaccine response in pregnant and lactating women: a cohort study. *American Journal of Obstetrics and Gynecology* (2021 Mar 25)

## Studies Confirm COVID-19 mRNA Vaccines Safe, Effective for Pregnant Women

- Studies show that the COVID-19 mRNA vaccines now available in the U.S. appear to be completely safe for pregnant women.
- The women had good responses to the vaccines, producing needed levels of neutralizing antibodies and immune cells (memory T cells).

Collier AY et al. Immunogenicity of COVID-19 mRNA vaccines in pregnant and lactating women. *JAMA* (2021 May 13)

Shanes ED et al. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccination in pregnancy: Measures of immunity and placental histopathology. *Obstet Gynecol.* (2021 May 11)



U.S. Department of Health and Human Services

**NIH News**  
National Institutes of Health

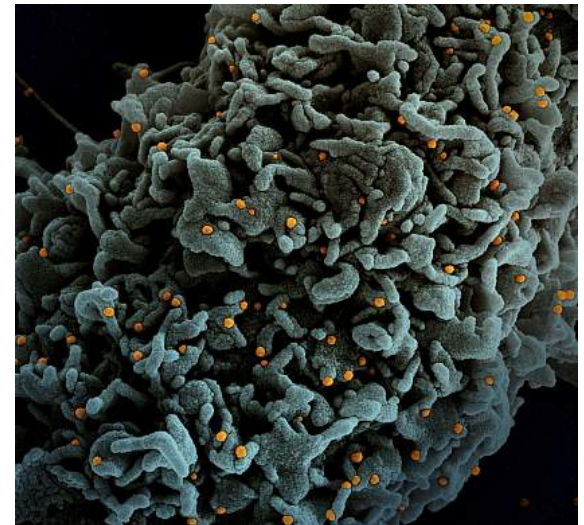
## NIH Clinical Trial Evaluating Moderna COVID-19 Variant Vaccine Begins

*Early-stage trial to evaluate safety and  
immunogenicity*

National Institute of Allergy and  
Infectious Diseases (NIAID)

<http://www.niaid.nih.gov>

March 31, 2021



Credit: NIAID





U.S. Department of Health and Human Services

**NIH News**

National Institutes of Health

# NIH Clinical Trial Evaluating Mixed COVID-19 Vaccine Schedules Begins

National Institute of Allergy and  
Infectious Diseases (NIAID)

<http://www.niaid.nih.gov>

June 1, 2021



Credit: NIH

# Researching COVID to Enhance Recovery (RECOVER)



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