National Institutes of Health Update

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June 2021
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

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.
  
  [Website Link]  
<table>
<thead>
<tr>
<th>Company</th>
<th>Platform</th>
<th>Product</th>
<th>Dose, schedule</th>
<th>Status</th>
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</thead>
<tbody>
<tr>
<td>moderna</td>
<td>mRNA</td>
<td>2P-stabilized Spike, TM, Fl</td>
<td>2 doses (0, 28)</td>
<td>EUA issued; BLA submission 6/1/21; adolescent data (ages 12-17) submitted to FDA in June; enrolling ages 6mths-11yrs</td>
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<tr>
<td>Biontech Pfizer</td>
<td>mRNA</td>
<td>Stabilized SARS-CoV-2 Spike</td>
<td>2 doses (0, 21)</td>
<td>EUA issued and expanded to adolescents (12-15yrs); BLA submission 5/7/21; enrolling ages 6mths-11yrs</td>
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<tr>
<td>AstraZeneca</td>
<td>Ad Vector</td>
<td>ChAdOx1 wild type Spike; ΔF; TM Ratio 2:1 Vaccine: Placebo</td>
<td>2 doses (0, 28)</td>
<td>Ph3 fully enrolled</td>
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<tr>
<td>Janssen</td>
<td>Ad Vector</td>
<td>Ad26; stabilized Spike; ΔF; TM</td>
<td>1 dose</td>
<td>EUA issued</td>
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<td>Novavax</td>
<td>Recombinant protein</td>
<td>Stabilized trimer Spike, ΔF; TM; Matrix M Adjuvant Ratio 2:1 Vaccine: Placebo</td>
<td>2 doses (0, 21)</td>
<td>Ph3 cross-over vacc placebo recip ongoing; adolescent expansion underway (ages 12-17)</td>
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<tr>
<td>GSK Sanofi</td>
<td>Recombinant protein</td>
<td>Stabilized Trimer Spike, ΔF; TM AS03 Adjuvant</td>
<td>2 doses (0, 21)</td>
<td>Phase 3 trial began 5/27/21; 2-stage design with initial stage testing adjuvanted monovalent; stage 2 adjuvanted bivalent for B.351 variant</td>
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Pediatric COVID-19 Vaccines

May 10, 2021

The Washington Post

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

Carolyn Y. Johnson

June 10, 2021

CNN

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

Ben Tinker and Virginia Langmaid
- 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 (Swab your Nose to Find inFection) to assess asymptomatic viral shedding of SARS-CoV-2.
  - First volunteers enrolled on June 1.
COVID-19 Vaccines and Pregnancy

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.

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)

NIH Clinical Trial Evaluating Moderna COVID-19 Variant Vaccine Begins

*Early-stage trial to evaluate safety and immunogenicity*

Credit: NIAID
NIH Clinical Trial Evaluating Mixed COVID-19 Vaccine Schedules Begins

Credit: NIH
Long-term effects of COVID are real. Join the search for answers.

Have questions about the long-term health effects of the virus? Start by learning about PASC.

https://recovercovid.org/