National Institutes of Health Update

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National Institute of Allergy and Infectious Diseases



National Institute of Allergy and Infectious Diseases (NIAID) http://www.niaid.nih.gov May 6, 2022

NIH Launches Clinical Trial of Epstein-Barr Virus Vaccine

- Phase 1 clinical trial evaluating safety and immune response of investigational vaccine for Epstein-Barr virus (EBV)
- Enrolling 40 healthy adults ages 18-29
 - Half with evidence of prior EBV infection
- Conducted at NIH Clinical Center in Bethesda, MD

Pandemic Response Repository through Microbial and Immune Surveillance and Epidemiology (PREMISE)



https://www.niaid.nih.gov/news-events/blog

Researching COVID to Enhance Recovery (RECOVER)



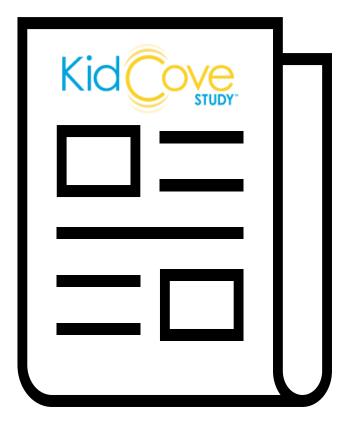
RECOVER Adult Study Protocol Available 🖾

The full RECOVER research protocol, or study plan, for adults taking part in RECOVER studies is now available. The study protocol serves as the RECOVER research playbook, enabling researchers to speak the same language, use the same methods, and examine the same types of data. We are finished planning the adult study protocol, but the protocol may change over time as we learn more. If the protocol is updated, we will share it on the RECOVER website, recovercovid.org. A version of the protocol in easier to understand language will be available soon.

recoverCOVID.org • March 28, 2022



KidCove: Pediatric COVID-19 Vaccine Study



- Trial of mRNA-1273 in children between ages of 6 months to <12 years
- 6 months to under 6 years:
 - Two 25 µg doses showed robust neutralizing antibody response
 - mRNA-1273 was generally well tolerated
 - April 28, 2022: EUA request submitted



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The NEW ENGLAND JOURNAL of MEDICINE



ORIGINAL ARTICLE

Evaluation of mRNA-1273 Covid-19 Vaccine in Children 6 to 11 Years of Age

C. Buddy Creech, M.D., M.P.H., Evan Anderson, M.D., Vladimir Berthaud, M.D., M.P.H., Inci Yildirim, M.D., Ph.D., Andrew M. Atz, M.D., Ivan Melendez Baez, M.D., Daniel Finkelstein, M.D., Paul Pickrell, M.D., Judith Kirstein, M.D., Clifford Yut, M.D., Ronald Blair, M.D., Robert A. Clifford, M.D., <u>et al.</u>, for the KidCOVE Study Group^{*}

- Two 50-µg doses were found safe and effective in inducing immune responses and preventing COVID-19 in children 6 to 11 years
- These responses were noninferior to those in young adults

CB Creech, *et al.* Evaluation of mRNA-1273 covid-19 vaccine in children 6 to 11 years of age. *New England Journal of Medicine* (2022 May)



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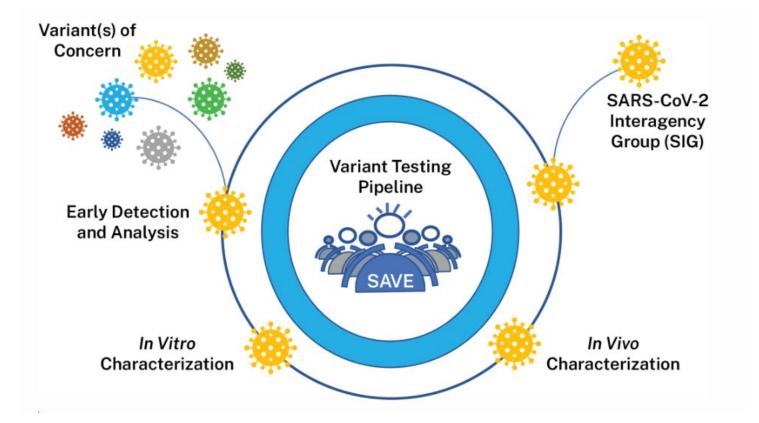


National Institute of Allergy and Infectious Diseases (NIAID) http://www.niaid.nih.gov May 18, 2022

NIAID Announces Antiviral Drug Development Awards

Antiviral Drug Discovery (AViDD) Centers for Pathogens of Pandemic Concern

SARS-CoV-2 Assessment of Viral Evolution (SAVE) Program



https://www.niaid.nih.gov/research/sars-cov-2-assessment-viral-evolution-program MM DeGrace *et al.* Defining the risk of SARS-CoV-2 variants on immune protection. *Nature* (2022 March)

COVAIL Clinical Trial Begins

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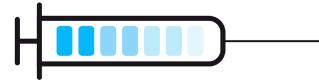
NIH Begins Clinical Trial Evaluating Second COVID-19 Booster Shots in Adults

Study Includes Multiple Variant Vaccines

March 31, 2022

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- Ph. 2 trial evaluating COVID-19 booster shots to understand if different vaccine regimens can broaden immune response in vaccinated adults
- For more information, visit ClinicalTrials.gov and search identifier <u>NCT05289037</u>



Vaccine booster shots... in progress



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