

Project NextGen Awards Over \$1.4 Billion to Develop the Future of COVID-19 Vaccines and Therapeutics

Funding includes \$1 billion for vaccine trials, \$326 million for a new monoclonal antibody and \$100 million for novel technologies.

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Today, the U.S. Department of Health and Human Services (HHS), through the Administration for Strategic Preparedness and Response (ASPR), awarded more than \$1.4 billion for Project NextGen to support the development of a new generation of tools and technologies to protect against COVID-19 for years to come.

The awards announced today follow extensive coordination with industry partners and include support for clinical trials that will enable the rapid development of even more effective and longer-lasting coronavirus vaccines, a new monoclonal antibody, and transformative technologies to streamline manufacturing processes.

“Project NextGen is a key part of the Biden-Harris Administration’s commitment to keeping people safe from COVID-19 variants,” said HHS Secretary Xavier Becerra. “These awards are a catalyst for the program – kickstarting efforts to more quickly develop vaccines and continue to ensure availability of effective treatments.”

Project NextGen, a \$5 billion initiative led by ASPR’s Biomedical Advanced Research and Development Authority (BARDA) in partnership with the National Institute of Allergy and Infectious Diseases (NIAID), coordinates across the federal government and the private sector to advance innovative vaccines and therapeutics into clinical trials, regulatory review, and potential commercial availability for the American people. The project builds on a better understanding of COVID-19 – with HHS developing, using, and constantly re-evaluating the strengths and weaknesses of current vaccines and therapeutics for over three years.

“As the virus continues to evolve, we need new tools that keep pace with those changes,” said Assistant Secretary for Preparedness and Response Dawn O’Connell. “Project NextGen combines the research and development expertise at HHS with the lessons we have learned about the virus throughout the pandemic – strengthening our preparedness for whatever comes next.”

The awards announced today include the following actions:

- \$1 billion to four BARDA Clinical Trial partners to support vaccine Phase IIb clinical trial studies: ICON Government and Public Health Solutions, Inc of Hinckley, Ohio; Pharm-Olam, LLC, of Houston, Texas; Technical Resources Intl (TRI), Inc, of Bethesda, Maryland; and Rho Federal Systems, Inc., Durham, North Carolina.
- \$326 million to Regeneron to support the development of a next-generation monoclonal antibody for COVID-19 prevention.
- \$100 million to Global Health Investment Corp. (GHIC), the non-profit organization managing the BARDA Ventures investment portfolio to expand investments in new technologies that will accelerate responses in the future.
- \$10 million to Johnson & Johnson Innovation (JLABS) for a competition through Blue Knight, a BARDA-JLABS partnership.

The awards to BARDA's Clinical Studies Network will speed the development of new vaccine candidates, providing a network of at-the-ready trials with the flexibility to pivot to the most promising new vaccines as they mature. The public can expect to see clinical trials for new vaccine candidates targeting longer-lasting protection against future variants as early as this winter under Project NextGen.

HHS' partnership with Regeneron is advancing its efforts to prevent COVID-19 infections by developing a novel monoclonal antibody that will protect people who do not respond to or cannot take existing vaccines – a critical need and current gap in COVID-19 therapeutics. HHS and Regeneron expect that the new monoclonal antibody will enter clinical trials this fall.

The remaining awards will fund technologies that enable more efficient development and manufacturing strategies – accelerating development timelines across the board and bolstering future vaccine and therapeutic availability.

In parallel with the awards announced today, HHS continues to engage with potential partners and expects to announce additional awards before the end of this fiscal year.

To learn more about Project NextGen, visit medicalcountermeasures.gov/nextgen/.

This news release was published by the Department of Health and Human Services on August 22, 2023.

<http://beta.docker.realhealthmag.com/article/project-nextgen-awards-14-billion-develop-future-covid19-vaccines-therapeutics>