

Health Agencies Update

Study Aims to Identify Drugs That Could Be Repurposed for COVID-19

The National Institute of Allergy and Infectious Diseases (NIAID) recently launched a [study](#) to determine whether drugs that are [already approved](#) or in the late stage of clinical development might merit testing in larger clinical trials as a coronavirus disease 2019 (COVID-19) treatment.

The ACTIV-5 Big Effect Trial is a collaboration with the [Accelerating COVID-19 Therapeutic Interventions and Vaccines \(ACTIV\) program](#), a public-private partnership with the National Institutes of Health. The phase 2 randomized, double-blind clinical trial will compare different therapies to a common control group to see which drugs, if any, have relatively large treatment effects.

Approximately 100 adult volunteers hospitalized with COVID-19 will be assigned to each study group. As many as 40 US medical centers will participate, with each testing up to 3 drugs at a time.

"This study design is both an efficient way of finding...promising treatments and eliminating those that are not," NIAID Director Anthony Fauci, MD, said in a [statement](#).

In the initial 2 study groups, all participants will receive the antiviral remdesivir, recently [approved](#) by the US Food and Drug Administration and considered to be standard care for hospitalized patients with COVID-19. In 1 group, patients will also be randomized to receive either the monoclonal antibody risankizumab (marketed as [Skyrizi](#)) to treat plaque psoriasis, or placebo. In the other group, patients will be randomized to the investigational monoclonal antibody [lenzilumab](#), which has been developed to treat cytokine storm, a hyper-immune response, or placebo.

The study's primary end point is the clinical efficacy of the investigational treatments compared with the control groups based on participants' status on the eighth day after treatment. The secondary end point is the length of time for each participant to recover from COVID-19.

After discharge from the hospital, participants will have study visits on days 15, 22, and 29, either in person or by phone.

Importance of Patient Input in Designing CRISPR Trials

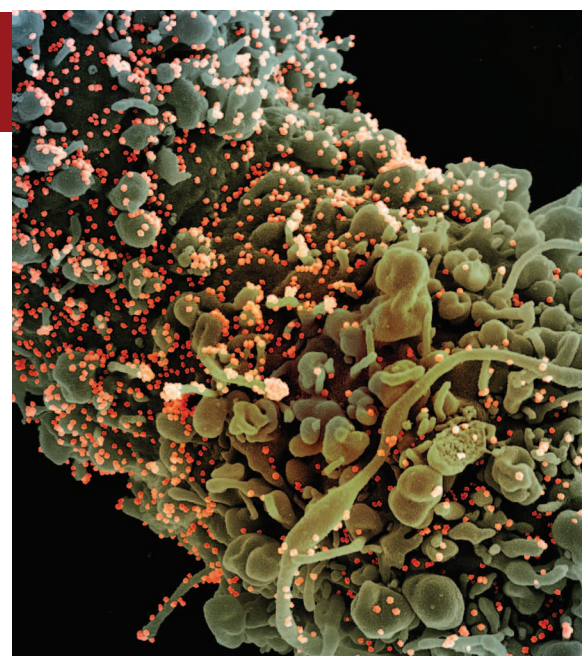
Clinical trials of genome editing to treat sickle cell anemia must be designed with input from patients and their parents and physicians, a recent [study](#) by National Human Genome Research Institute (NHGRI) scientists concluded.

Two methods of CRISPR (clustered regularly interspaced short palindromic repeats) somatic genome editing that could substantially reduce the symptoms of or potentially cure sickle cell disease—which affects more than 100 000 US residents—are being investigated, the authors wrote. Clinical trials will be necessary to advance the potential treatment, but, if not adequately informed, seriously ill patients could overestimate the benefits of early-phase studies while underestimating the risks.

"By talking to sickle cell disease stakeholders ahead of time, we can learn more about their values and hopefully do a better job of pinpointing what kinds of information will be most useful to potential research participants as they make a very difficult decision," coauthor Sara Hull, PhD, director of the NHGRI Bioethics Core, said in a [statement](#).

Hull and her coauthors sought the views of adults with sickle cell disease as well as parents and physicians of individuals with the condition—a total of 110 people. Study participants, who lived in the mid-Atlantic and southern US, were asked to complete 2 surveys, watch a 14-minute educational video about genome editing, and take part in focus groups.

All participants said they wanted informed consent to include CRISPR adverse effects, and many wanted to know how it works and how it could affect their quality of life. In addition, participants demonstrated higher genetic literacy than had been estimated. However, the authors noted that participants had been recruited from national sickle cell conferences and advocacy groups, so they might have been more actively involved in clinical trial research than the general sickle cell disease population.



Researchers are studying approved drugs to determine their efficacy as coronavirus disease 2019 treatments.

Aid for American Indian, Alaska Native Individuals Who Want to Quit Smoking

The Indian Health Service (IHS) recently [launched](#) SmokefreeTXT, a mobile messaging tool to help American Indian and Alaska Native individuals quit smoking.

Sacred tobacco is used for prayer, healing, and rituals in many Native cultures, but the use of commercial tobacco by American Indians and Alaska Natives remains significantly higher than the national average, according to US Centers for Disease Control and Prevention [data](#).

Anyone in the US who wants to quit smoking can use [SmokefreeTXT](#), a free program developed in collaboration with the National Cancer Institute. However, the program now has special messaging for American Indians and Alaska Natives, who can sign up by texting NATIVE to 47848.

For 6 to 8 weeks, SmokefreeTXT will send 3 to 5 text messages daily to support efforts to quit smoking. Anyone who needs more help can text a keyword such as "CRAVE," "MOOD," or "SLIP" back to SmokefreeTXT.

Although the IHS prohibits tobacco use at its properties, it allows tobacco for ceremonial purposes. — Rita Rubin, MA

Note: Source references are available through embedded hyperlinks in the article text online.