According to the **World Health Organization**, there are more than 20 vaccines for COVID-19 in development with several therapeutics currently in clinical trials. While the majority of these vaccine or treatment candidates are in preclinical development, the following details what several drug makers are working on and where they are in the development process. See below for the FDA categories describing the five clinical trial stages.

In the U.S., several companies have received funding from the **Biomedical Advanced Research and Development Authority (BARDA)**, a division of the Department of Health and Human Services, and the **National Institute of Allergy and Infectious Diseases (NIAID)**, a division of the National Institutes of Health. Some companies

have received funding from **Coalition for Epidemic Preparedness Innovations (CEPI)**, a global alliance financing and coordinating vaccine development against emerging infectious diseases. Some companies are funding their own development or partnering with other life sciences companies.

Novavax, Inc. was awarded funding from CEPI to support its efforts to develop a COVID-19 vaccine. A Phase I clinical trial is expected to initiate in late spring of 2020. Novavax is currently assessing multiple recombinant nanoparticle vaccine candidates leveraging its recombinant protein nanoparticle technology platform to generate antigens derived from the coronavirus spike (S) protein. The company will also leverage its Matrix-M adjuvant to enhance immune responses.

GlaxoSmithKline is developing a pandemic adjuvant platform for vaccines. GSK provides the CEPI-funded University of Queensland with access to its vaccine adjuvant platform technology, which is believed to strengthen the response of a vaccine and limit the amount of vaccine needed per dose. Also, Clover Biopharmaceuticals Inc., a Chinese biotechnology company, is using adjuvant technology in combination with its vaccine candidate, COVID-19 S-Trimer, in preclinical studies.

Inovio Pharmaceuticals Inc. is developing INO-4800, a DNA-based vaccine currently in preclinical trials, with small-scale manufacturing underway. The company plans to begin clinical trials in the U.S. with 30 participants in April and plans to launch trials in China and South Korea. The company has a total of 3,000 doses prepared for the trials in the three countries. Inovio expects to have the first trial results in the fall and to

have 1 million doses of the vaccine ready for additional clinical trials or emergency use by the end of the year.

Johnson & Johnson is working on identifying and testing a vaccine candidate with BARDA, with both organizations providing funding for R&D and BARDA funding the Phase I trials. J&J's AdVac and PER. C6 technologies are used to improve the development process for a vaccine and were also used to develop J&J's experimental Ebola vaccine. J&J is also partnering with BARDA on a project that aims to screen existing antiviral medications, including experimental or approved therapies, that may be effective against COVID-19.

Moderna Inc. is developing mRNA-1273, a RNA-based vaccine candidate against COVID-19, which is in preclinical development. Moderna has received funding from CEPI. According to the company, on February 24, it shipped the first batch of mRNA-1273 to the NIAID for a Phase I clinical trial in the U.S. The open-label Phase I trial will enroll 45 healthy adult patients to test mRNA-1273 as a vaccine for COVID-19. The trial is expected to conclude June 1, 2021. Participants will be followed for one year.

Regeneron Pharmaceuticals Inc. is developing monoclonal antibodies as treatments for COVID-19, currently in preclinical development. The company's VelocImmune platform uses genetically-engineered mice with humanized immune systems.

Sanofi is working with BARDA to test a preclinical vaccine candidate for severe acute

respiratory syndrome (SARS) for COVID-19 using its recombinant DNA platform. The Sanofi Pasteur business acquired this candidate through its $750 million acquisition of Protein Sciences in 2017. The company aims to initiate a Phase I clinical trial between March 2021 and August 2021.

Takeda Pharmaceutical Co. is developing TAK-888 as a treatment for COVID-19. Currently in preclinical development, the company plans to test hyperimmune globulins for people who are at high risk for infection. As part of its research, Takeda said it would need access to plasma from people who have recovered from COVID-19 or those who have received a vaccine if one is developed. Takeda plans to examine whether other therapies, both experimental or with regulatory approval, may have treatment potential.

Vir Biotechnology Inc. is collaborating with Shanghai-based WuXi Biologics to test monoclonal antibodies as a treatment for COVID-19. If the treatment is approved, WuXi will commercialize it in China, while Vir will have marketing rights for the rest of the world.

The following are the FDA categories for describing the clinical trial of a drug based on the study's characteristics, such as the objective and number of participants.

Phase 0: Exploratory study involving very limited human exposure to the drug, with no therapeutic or diagnostic goals (for example, screening studies, microdose studies)

Phase I: Studies that are usually conducted with healthy volunteers and that

emphasize safety. The goal is to find out what the drug's most frequent and serious adverse events are and, often, how the drug is metabolized and excreted.

Phase II: Studies that gather preliminary data on effectiveness (whether the drug works in people who have a certain disease or condition). Participants receiving the drug may be compared with similar participants receiving a different treatment, usually an inactive substance (placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.

Phase III: Studies that gather more information about safety and effectiveness by studying different populations and different dosages and by using the drug in

combination with other drugs.

Phase IV: Studies occurring after FDA has approved a drug for marketing. These include post-market requirement and commitment studies that are required of or agreed to by the sponsor. These studies gather additional information about a drug's safety, efficacy, or optimal use.