

# COVID 19

## A Look at Clinical Trials and Vaccines

There has been much talk about COVID-19 vaccines in development including the companies developing the vaccines, the technology used to develop these vaccines, and how far along each vaccine is in its journey through clinical trials.

To better understand the terminology used, and the various phases and types of clinical research and trials, we have assembled a definition of terms for the many different types of clinical research and clinical trial phases.

Additionally, we have assembled a chart listing the COVID-19 vaccines that have advanced to Phase 2 and Phase 3 trials.

### Phases of Clinical Trials: When Clinical Research is Used to Evaluate Medications and Devices

Clinical trials are a kind of clinical research designed to evaluate and test new interventions such as psychotherapy or medications. Clinical trials are often conducted in four phases. The trials at each phase have a different purpose and help scientists answer different questions.

- **Phase I trials**

Researchers test an experimental drug or treatment in a small group of people for the first time. The researchers evaluate the treatment's safety, determine a safe dosage range, and identify side effects.

- **Phase II trials**

The experimental drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.

- **Phase III trials**

The experimental study drug or treatment is given to large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.

- **Phase IV trials**

Post-marketing studies, which are conducted after a treatment is approved for use by the FDA, provide additional information including the treatment or drug's risks, benefits, and best use.

### Examples of Other Kinds of Clinical Research

Many people believe that all clinical research involves testing of new medications or devices. This is not true, however. Some studies do not

involve testing medications and a person's regular medications may not need to be changed. Healthy volunteers are also needed so that researchers can compare their results to results of people with the illness being studied. Some examples of other kinds of research include the following:

- A long-term study that involves psychological tests or brain scans
- A genetic study that involves blood tests but no changes in medication
- A study of family history that involves talking to family members to learn about people's medical needs and history.

Different types of clinical research are used depending on what the researchers are studying. Below are descriptions of some different kinds of clinical research.

**Treatment Research** generally involves an intervention such as medication, psychotherapy, new devices, or new approaches to surgery or radiation therapy.

**Prevention Research** looks for better ways to prevent disorders from developing or returning. Different kinds of prevention research may study medicines, vitamins, vaccines, minerals, or lifestyle changes.

**Diagnostic Research** refers to the practice of looking for better ways to identify a particular disorder or condition.

**Screening Research** aims to find the best ways to detect certain disorders or health conditions.

**Quality of Life Research** explores ways to improve comfort and the quality of life for individuals with a chronic illness.

**Genetic Studies** aim to improve the prediction of disorders by identifying and understanding how genes and illnesses may be related. Research in this area may explore ways in which a person's genes make him or her more or less likely to develop a disorder. This may lead to development of tailor-made treatments based on a patient's genetic make-up.

**Epidemiological Studies** seek to identify the patterns, causes, and control of disorders in groups of people.

An important note: some clinical research is "outpatient," meaning that participants do not stay overnight at the hospital. Some is "inpatient," meaning that participants will need to stay for at least one night in the hospital or research center.

Source: <https://www.fda.gov/patients/clinical-trials-what-patients-need-know/what-are-different-types-clinical-research>

## COVID-19 Vaccines Currently in Phase 2 and 3 Clinical Trials

Candidate	Sponsor	Trial Phase	Institution	Funding
Inactivated vaccine	Wuhan Institute of Biological Products; China National Pharmaceutical Group (Sinopharm)	Phase 3	Henan Provincial Center for Disease Control and Prevention	Ministry of Science and Technology, China
CoronaVac	Sinovac	Phase 3	Sinovac Research and Development Co., Ltd.	Sinovac Research and Development Co., Ltd.
mRNA-1273	Moderna	Phase 3	Kaiser Permanente Washington Health Research Institute	Operation Warp Speed; NIAID, BARDA (\$483 million)
Ad5-nCoV	CanSino Biologics	Phase 3	Tongji Hospital; Wuhan, China	CanSino Biologics
Bacillus Calmette-Guerin (BCG) live-attenuated vaccine; Calmette-Guerin (BCG) live-attenuated vaccine	University of Melbourne and Murdoch Children's Research Institute; Radboud University Medical Center; Faustman Lab at Massachusetts General Hospital	Phase 2/3	University of Melbourne and Murdoch Children's Research Institute; Radboud University Medical Center; Faustman Lab at Massachusetts General Hospital	Murdoch Children's Research Institute; UMC Utrecht
AZD1222/Covishield	The University of Oxford; AstraZeneca; IQVIA; Serum Institute of India	Phase 2/3	The University of Oxford, the Jenner Institute	Operation Warp Speed; UK Ministry of Health; The University of Oxford; BARDA
BNT162	Pfizer, BioNTech	Phase 2/3	Multiple study sites in Europe and North America	Pfizer, BioNTech

Source: <https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker>