

# Current scenario of vaccination for covid-19

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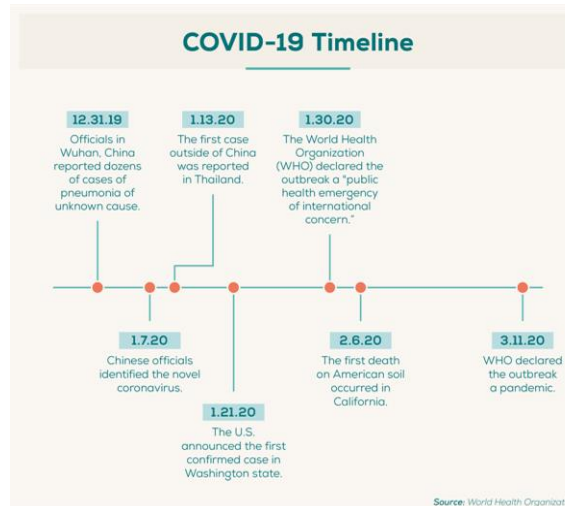
**Abstract** - The current COVID-19 pandemic has urged the scientific community throughout the world to find a cure for the disease therapeutics and vaccines to control SARS-CoV-2. Some of the published investigations mostly on SARS-CoV and on MERS have taught lessons on developing the vaccination strategies for this novel coronavirus. It has also revealed the fact that SARS-CoV-2 uses the same receptor as SARS-CoV on the human cell and is approximately 80% similar genetically to SARS-CoV. Although the efforts on COVID-19 vaccines started very early, initially in China, as soon as the outbreak of coronavirus started and then world-over as the disease was declared a pandemic by WHO. But we got the vaccine at a very later stage. This is because a COVID-19 vaccine will require validation of efficacy because the target vaccine population includes high-risk individuals i.e. senior citizens, over the age of 60, particularly those with co-morbid conditions, frontline healthcare workers etc. Various types of vaccine development are available namely: virus vectored vaccines, genetic vaccines, and monoclonal antibodies, protein subunit vaccines, for passive immunization. The COVID-19 pandemic is the most devastating one in the last 100 years after the Spanish flu which requires the speedy evaluation of the various approaches for competence to provide protective immunity and safety. This review is aimed at providing an overview of the efforts dedicated to an effective vaccine for this novel coronavirus which has crippled the entire world in terms of life, economy, and human health.

## INTRODUCTION

The figures given below describes briefly about the current variants of the coronavirus. The various countries in which the given variant was first documented. This gives an information that the coronavirus has a very high rate of mutation and also scientists are trying to develop the vaccines which in various combinations are effective on most of the variants which are now seen in this virus.

### CURRENTLY DESIGNATED VARIANTS OF CONCERN

WHO label	Pango lineage*	GISAID clade	Next strain clade	Additional amino acid changes monitored <sup>o</sup>	Earliest documented samples	Date of designation
Alpha	B.1.1.7 #	GRY	20I (V1)	+S:484K +S:452R	United Kingdom, Sep-2020	18-Dec-2020
Beta	B.1.351	GH/501Y.V2	20H (V2)	+S:L18F	South Africa, May-2020	18-Dec-2020
Gamma	P.1	GR/501Y.V3	20J (V3)	+S:681H	Brazil, Nov-2020	11-Jan-2021
Delta	B.1.617.2 <sup>s</sup>	G/478K.V1	21A	+S:417N	India, Oct-2020	VOI: 4-Apr-2021

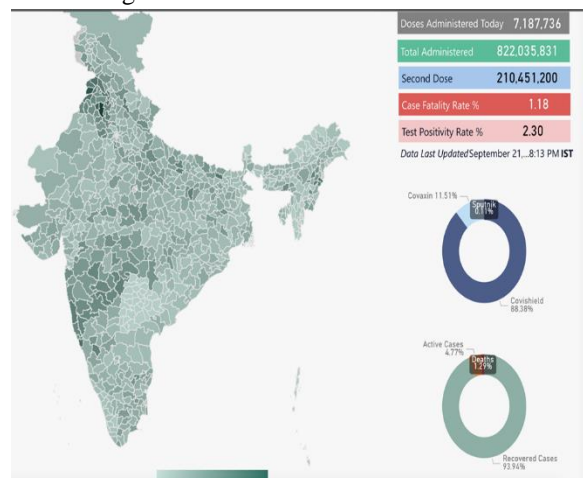


## COVID-19 VACCINE TRACKER IN INDIA

On January 16, 2021, the Government of India and State governments launched one of the most extensive vaccination drives against COVID-19, targeting 300 million priority beneficiaries comprising healthcare workers, frontline workers, and people above 50 years of age, and further expanding eligibility to those above 18 years of age in May 2021. With more than 83 crore COVID vaccines administered so far, India is going

strong in its fight against COVID-19. Detailed Operational Guidelines are supporting the mass vaccination effort, as well as a COVID-19 Vaccine Intelligence Network (Co-WIN) system to track beneficiaries on a real-time basis. The dashboards below visualize daily updates of data from CoWIN for the districts and parliamentary constituencies of India. District administrators, elected representatives, policymakers and the public-at-large can use this data to understand how vaccine distribution is progressing and respond effectively.

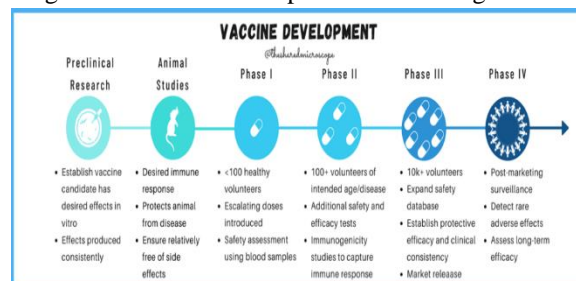
India reached a new milestone on Friday (17<sup>th</sup> Sept'21) by administering over 25 million (2.5 crore) doses of Covid-19 vaccines in a single day. The feat was achieved on the birthday of Prime Minister Narendra Modi. The over 25 million vaccine shots (administered on Friday 17<sup>th</sup> September, 2021) equals the entire population of Australia, is two-thirds the population of Canada, and five times the entire population of New Zealand, according to the central government. The Union health ministry said on Thursday that the special drive had raised India's overall vaccinations to more than 830 million. India, a country of nearly 1.4 billion people, has given at least one dose to more than 62% of eligible adults and two doses to about 21%.



### Vaccine Development, Testing, and Regulation

Vaccine development is a long, complex process, often lasting 10-15 years and involving a combination of public and private involvement. The current system for developing, testing, and regulating vaccines developed during the 20th century as the groups involved standardized their procedures and regulations.

### Stages of Vaccine Development and Testing



### Exploratory Stage

This stage involves basic laboratory research and often lasts 2-4 years. Federally funded academic and governmental scientists identify natural or synthetic antigens that might help prevent or treat a disease. These antigens could include virus-like particles, weakened viruses or bacteria, weakened bacterial toxins, or other substances derived from pathogens.

### Pre-Clinical Stage

Pre-clinical studies use tissue-culture or cell-culture systems and animal testing to assess the safety of the candidate vaccine and its immunogenicity, or ability to provoke an immune response. Animal subjects may include mice and monkeys. These studies give researchers an idea of the cellular responses they might expect in humans. They may also suggest a safe starting dose for the next phase of research as well as a safe method of administering the vaccine. Researchers may adapt the candidate vaccine during the pre-clinical state to try to make it more effective. They may also do challenge studies with the animals, meaning that they vaccinate the animals and then try to infect them with the target pathogen. Many candidate vaccines never progress beyond this stage because they fail to produce the desired immune response. The pre-clinical stages often last 1-2 years and usually involves researchers in private industry.

### Phase I Vaccine Trials

This first attempt to assess the candidate vaccine in humans involves a small group of adults, usually between 20-80 subjects. If the vaccine is intended for children, researchers will first test adults, and then gradually step down the age of the test subjects until they reach their target. Phase I trials may be non-blinded (also known as open-label in that the researchers and perhaps subjects know whether a vaccine or placebo is used). The goals of Phase 1

testing are to assess the safety of the candidate vaccine and to determine the type and extent of immune response that the vaccine provokes. In a small minority of Phase I vaccine trials, researchers may use the challenge model, attempting to infect participants with the pathogen after the experimental group has been vaccinated. The participants in these studies are carefully monitored and conditions are carefully controlled. In some cases, an attenuated, or modified, version of the pathogen is used for the challenge.

### Phase II Vaccine Trials

A larger group of several hundred individuals participates in Phase II testing. Some of the individuals may belong to groups at risk of acquiring the disease. These trials are randomized and well controlled, and include a placebo group. The goals of Phase II testing are to study the candidate vaccine's safety, immunogenicity, proposed doses, schedule of immunizations, and method of delivery.

### Phase III Vaccine Trials

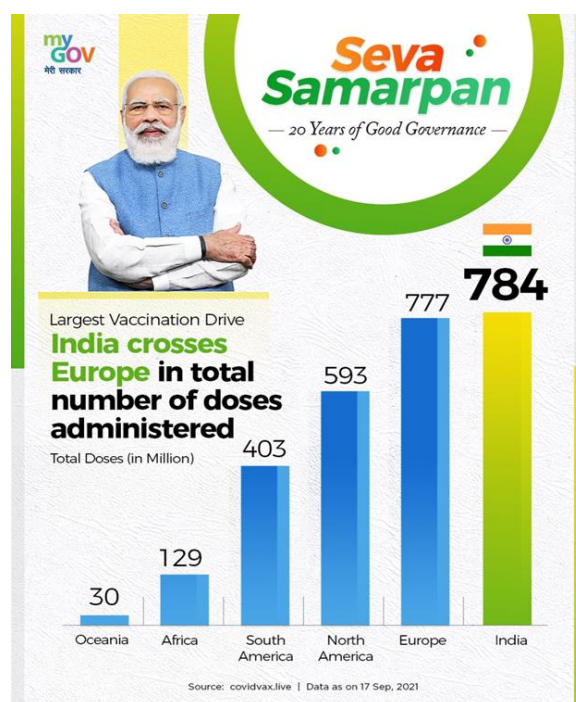
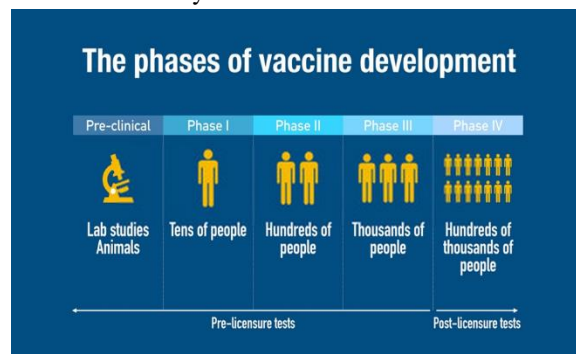
Successful Phase II candidate vaccines move on to larger trials, involving thousands to tens of thousands of people. These Phase III tests are randomized and double blind and involve the experimental vaccine being tested against a placebo (the placebo may be a saline solution, a vaccine for another disease, or some other substance). One Phase III goal is to assess vaccine safety in a large group of people. Certain rare side effects might not surface in the smaller groups of subjects tested in earlier phases. For example, suppose that an adverse event related to a candidate vaccine might occur in 1 of every 10,000 people.

### Next Steps: Approval and Licensure

After a successful Phase III trial, the vaccine developer will submit a Biologics License Application to the FDA. Then the FDA will inspect the factory where the vaccine will be made and approve the labeling of the vaccine. After licensure, the FDA will continue to monitor the production of the vaccine, including inspecting facilities and reviewing the manufacturer's tests of lots of vaccines for potency, safety and purity. The FDA has the right to conduct its own testing of manufacturers' vaccines.

### Phase IV Trials

Phase IV trial are optional studies that drug companies may conduct after a vaccine is released. The manufacturer may continue to test the vaccine



### TYPES OF VACCINE RESEARCH

Messenger RNA (mRNA) vaccine. This type of vaccine uses genetically engineered mRNA to give your cells instructions for how to make the S protein found on the surface of the COVID-19 virus. After vaccination, your immune cells begin making the S protein pieces and displaying them on cell surfaces. This causes your body to create antibodies. If you later become infected with the COVID-19 virus, these antibodies will fight the virus.

After delivering instructions, the mRNA is immediately broken down. It never enters the nucleus of your cells, where your DNA is kept. Both the Pfizer-

BioNTech and the Moderna COVID-19 vaccines use mRNA.

**Vector vaccine.** In this type of vaccine, genetic material from the COVID-19 virus is placed in a modified version of a different virus (viral vector). When the viral vector gets into your cells, it delivers genetic material from the COVID-19 virus that gives your cells instructions to make copies of the S protein. Once your cells display the S proteins on their surfaces, your immune system responds by creating antibodies and defensive white blood cells. If you later become infected with the COVID-19 virus, the antibodies will fight the virus.

Viral vector vaccines can't cause you to become infected with the COVID-19 virus or the viral vector virus. Also, the genetic material that's delivered doesn't become part of your DNA. The Janssen/Johnson & Johnson COVID-19 vaccine is a vector vaccine. AstraZeneca and the University of Oxford also have a vector COVID-19 vaccine.

**Protein subunit vaccine.** Subunit vaccines include only the parts of a virus that best stimulate your immune system. This type of COVID-19 vaccine contains harmless S proteins. Once your immune system recognizes the S proteins, it creates antibodies and defensive white blood cells. If you later become infected with the COVID-19 virus, the antibodies will fight the virus. Novavax is working on a protein subunit COVID-19 vaccine.

#### TYPES OF VACCINES IN INDIA

**Covishield /Astra Zeneca-** Viral vector-based vaccines differ from most conventional vaccines in that they don't actually contain antigens, but rather use the body's own cells to produce them. They do this by using a modified virus (the vector) to deliver genetic code for antigen, in the case of COVID-19 spike proteins found on the surface of the virus, into human cells. By infecting cells and instructing them to make large amounts of antigen, which then trigger an immune response, the vaccine mimics what happens during natural infection with certain pathogens - especially viruses. This has the advantage of triggering a strong cellular immune response by T cells as well the production of antibodies by B cells.



**Covaxin- Inactivated vaccines:**

It contains viruses whose genetic material has been destroyed by heat, chemicals or radiation so they cannot infect cells and replicate, but can still trigger an immune response. Inactivated virus vaccines also contain the disease-causing virus, or parts of it, but their genetic material has been destroyed. For this reason, they are considered safer and more stable than live attenuated vaccines, and they can be given to people with compromised immune systems. Even though their genetic material has been destroyed, inactivated viruses usually contain many proteins which the immune system can react to.



**Sputnik V-** The Russian COVID-19 vaccine Sputnik V (Gam-COVID-Vac):

It is an adenoviral-based, two-part vaccine against the SARS-CoV-2 coronavirus. Initially produced in Russia, Sputnik V uses a weakened virus to deliver small parts of a pathogen and stimulate an immune response. It is a vector vaccine based on adenovirus DNA, in which the SARS-CoV-2 coronavirus gene is integrated. Adenovirus is used as a "container" to deliver the coronavirus gene to cells and start synthesizing the new coronavirus's envelope proteins, "introducing" the immune system to a potential enemy. The cells will use the gene to produce the spike protein.

COVID-19 VACCINES COMPARISON						
	COUNTRY	TYPE	DOSES	EFFECTIVENESS	STORAGE	COST PER DOSE
Pfizer/ BioNTech		mRna	2x	95%	-70 C	\$19.5
Moderna		mRna	2x	95%	-70 C	\$32-\$37
Oxford/ AstraZeneca		Viral vector	2x	90%	2-8 C	\$3-\$4
Sputnik V		Viral vector	2x	92%	2-8 C	\$10
CoronaVac		Inactivated virus	2x	50-83%	2-8 C	\$13.6-\$40
Sinopharm		Inactivated virus	2x	80%	2-8 C	Up to \$75
Johnson & Johnson		Viral vector	1x	66%*	2-8 C	\$10
Novavax		Subunit vaccine	2x	89%	2-3 C	\$16
CanSinoBIO		Viral Vector	1x	66%*	2-8 C	TBD
Anhui Zhifei Longcom		Subunit vaccine	2x	TBD	2-8 C	TBD
Covishield		Viral Vector	2x	65%	2-8 C	\$3.3
Covaxin		Inactivated Virus	2x	80.6%	2-8 C	\$3.8

\* Efficacy against symptomatic disease, and not against infection  
TBD= To be determined  
\*Prices based on information available in Media  
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### LIMITATIONS

Considering the severity of the pandemic, which has forced a complete shut-down of the global economy, speedy vaccine development is necessary. The amount of time required for the clinical trial poses a big problem for the usage of the vaccine. The viral genome is vulnerable to mutations and can undergo the antigenic shift and the antigenic drift, as it continues to spread from one population to the next. The mutations may vary according to the environmental conditions of a geographical area, and the population density. This poses a great challenge for the scientific community for the development of highly effective vaccine against all the variants of the virus.

### CONCLUSION

Scientists across the globe are joining hands for the innovative tie-ups with both the pharmaceutical companies and the medical start-ups to develop vaccines, and devices to impede the progress of this pandemic. A large number of COVID-19 vaccine

candidates have already been identified. Despite the undergoing efforts, a definitive answer does not exist. The process of vaccine development is quite time-consuming and laborious with various stages, including the pre-clinical stage, and clinical development which is a three-phase process.

This novel Coronavirus has therefore forced the scientific community to use unconventional ways to develop the vaccine at faster pace. The vaccine must be suitable for all ages, children, old age people, pregnant, and lactating women and should provide a rapid onset of protection with a single dose and should be safe for at least up to one year of administration.

In India alone, six biotech ventures i.e. Serum Institute of India, Zydus Cadila, Biological E, Indian Immunologicals, Bharat Biotech, and Mynvax are working in collaboration with various international vaccine developers.

The need of the hour is to develop a safe and effective COVID-19 vaccine which can induce an appropriate immune response to terminate this pandemic. It is the universal priority to spot the international funding mechanisms to support the development, manufacturing, and stockpiling of the coronavirus vaccines.

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