

How to Develop a Virus Vaccine

A vaccine exposes the body to an altered, safe version of a disease-causing virus, prompting the immune system to produce antibodies—proteins that can stop the real pathogen from infecting cells. The immune system then remembers how to fight the invader. Scientists can use different methods to create a chemical vaccine formulation, which they then test for safety and efficacy.



Create a Chemical Serum

The traditional approach inserts a modified version of the virus, or pieces of it, into a solution injected into the body. But the method is slow. Newer genetic engineering approaches insert a blueprint of the virus's genes into the solution. This method is faster but less proved.

Adapt it for a vaccine

Map the virus's genetic sequence

Genetically engineer particular virus genes and capture their blueprint

Weaken the virus (attenuated)

Kill the virus (inactivated)

Use isolated pieces of the virus (subunits)

Embed blueprint in DNA plasmid

Embed blueprint in RNA lipid

Embed blueprint in an adenovirus



Put particles into a solution, then test



Test in Animals and People

Testing starts in lab dishes and animals, then proceeds to humans, advancing from a handful to tens of thousands. If the vaccine causes serious side effects or does not produce antibodies or protect large numbers of people, it is abandoned.

PRECLINICAL TRIALS

Test in lab cultures and animals

Is it too toxic?



No

Yes

Does it prompt the immune system's cells to produce antibodies that will identify and attach to the virus?

No

Stop testing

CLINICAL TRIALS

Human testing

Phase 1:
Is the vaccine safe?
Are bad side effects avoided?
Does the immune system produce antibodies?

People tested: 10–100

No

Yes

Phase 2:
Is the vaccine safe?
Is the immune response strong?
Is the dosage correct?

People tested: 100s

No

Yes

Phase 3:
Does it safely prevent infection and disease across a large number of people?

People tested: 10,000s +

Yes

Production
A successful vaccine must be approved by regulators, then manufactured in volume and tested for product quality.

