Research and Development of a new vaccine

On average, it takes between **10 to 15 years to research & develop a vaccine.**

Vaccines are intended for use in healthy individuals as a disease preventive measure, and are therefore different to conventional drugs, which are aimed at the treatment of an existing condition. Safety is paramount for a vaccine. Vaccine clinical trials must be able to demonstrate both that a vaccine is safe and that it is effective in preventing disease. This means that a higher number of subjects will be required for vaccine clinical trials than for traditional drug trials. For these reasons, before a vaccine is licensed and brought to market it undergoes a long and rigorous period of research followed by many years of testing.

Discovery and Pre-clinical trials

1 to 10 years

Understanding the disease, the pathogenesis and the immune mechanisms of protection. Identifying vaccine composition and evaluating the vaccine candidate efficacy and safety profile using various assays and models - with both in vitro and in vivo tests being performed.

Non-clinical Safety Evaluation

1 – 2 years

In depth testing of the vaccine candidate's safety in laboratory and in vivo models, according to regulatory guidelines.

Clinical trials Phase 1

12 – 18 months

The candidate vaccine is tested in a small number of healthy individuals (20 – 50) to determine whether it is safe and can generate an immune response in humans.

Clinical trials Phase 2

2 or more years

The candidate vaccine is administered to a larger group of individuals (100-300) to further confirm its safety and immunogenicity. This phase explores in detail the optimal dose and might provide initial evidence of the vaccine's ability to protect against the target infection.

Clinical trials Phase 3

3 to 5 years

The most promising vaccine candidate is tested in thousands of individuals (3,000 to 5,000) to collect conclusive evidence of its ability to protect against the target infection. Additional information is collected on its safety and potential for causing rare side effect, not seen in smaller studies.

Registration of the vaccine in Europe

1 – 2 years

Documentation submission, evaluation and approval by the European Medicines Agency, or other relevant National Competent Authorities, for a license to market the vaccine and make it available in countries around the world.

Pharmacovigilance

Throughout the entire life of the vaccine

Pharmacovigilance activities take place to carry on a strict safety supervision of the vaccines already introduced to the market. It detects, assesses, understands, prevents and communicates any reported side effects following immunisation, or immunisation-related issues.

Reference:
https://www.ifpma.org/wp-content/uploads/2019/07/IFPMA-ComplexJourney-2019_FINAL.pdf