Immunisation Research and Development

Vaccines and preventive monoclonal antibodies (mAbs)

On average, immunisation research and development **takes between 10 to 15 years**

Immunisation differs from treatment in that it is intended as a disease preventive measure rather than aimed at treating an existing condition. Since it is indicated for broad population use in typically healthy and sometimes vulnerable people, tolerance for even rare side effects is extremely low. For these reasons, before a vaccine or a preventive monoclonal antibody (mAb) is licensed and brought to market it undergoes a long and rigorous period of research followed by many years of testing. Demonstrating that a candidate is safe and efficacious in preventing disease requires clinical trials in thousands to tens of thousands of healthy volunteers followed for long period of times and constant monitoring while on the market.

Discovery and Pre-clinical Phase

1 to 10 years

Understanding the pathogen, the disease, and immune mechanisms of protection. Designing the vaccine or preventive monoclonal antibody (mAb) and evaluating its efficacy and safety profile using various assays and models - performing *in vitro* and *in vivo* tests.

Non-clinical Safety Evaluation

1 – 2 years

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

Clinical trials Phase 1

12 – 18 months

The candidate is tested in a small number of healthy individuals (20 – 200) to determine whether it is safe and immunogenic (i.e., can generate an immune response) in humans.

Clinical trials Phase 2

2 or more years

The candidate is administered to a larger group of individuals (100-2,000) to further confirm its safety and immunogenicity. This phase explores in detail the optimal dose and might provide initial evidence of the candidate's efficacy (i.e., ability to protect against the target disease).

Clinical trials Phase 3

3 to 5 years

The most promising candidate is tested in thousands of individuals (3,000 to 50,000) to collect conclusive evidence of its ability to protect against the target disease. Additional information is collected on its safety and potential for causing rare side effect, not seen in smaller studies.

Registration 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 or mAb and make it available in countries around the world.

Post-Marketing Surveillance

Throughout the entire life of the product

Pharmacovigilance activities take place to carry on a strict safety supervision of the vaccines or mAbs already introduced to the market. These aim to detect, assess, understand, prevent, and communicate any reported side effects following immunisation, or immunisation-related issues.

Additionally, effectiveness monitoring studies may be performed to ensure immunisation remains efficacious in real-world conditions and in specific sub-populations.