

Vaccine Development for the COVID-19

Several disasters over the past century have highlighted the need for strong and accurate scientific innovations worldwide. The novel 2019 SARS-Cov-2 coronavirus disease that has hit over 200 countries has been described as one of the largest pandemics in recent decades. Although its source is not known, researchers and scientists across the globe have gone flat-out on research to mitigate and find solutions through the use of biological and biotechnological tools to develop interventions such as drugs and vaccines and save lives.

The research and development of a vaccine is a tedious and lengthy process that can take at least five to 20 years before it can be made available. The process involves many steps including laboratory tests on animals to determine the safety and efficacy of preventing the disease (*The History of Vaccines: vaccine development, testing and regulation*). The severity of the COVID-19 pandemic means that we need to fast-track the development of therapeutic strategies including vaccines. This means that, there should be put in place, very stringent biosafety measures that should ensure that all research work that is being done is ethically sound and within the confines of the laws that govern biomedical research.

A key pressure point in the development of a vaccine against the COVID-19 virus is time. Considering the continual spreading of the virus and the increasing number of mortalities, time is not a luxury that we possess. Various sections of society have debated how long it will take to develop an effective vaccine against Covid-19. While the optimists have this pegged at 18 months, the pessimists debate that we are looking at 2036. The clinical development of a vaccine for humans follows the same general pathways as other drugs (Fig 1).



Figure 1: Steps involved in the development of vaccines

Preclinical and clinical stages involve a series of other steps highlighted in fig 2. As can be noted clinical testing is involves human testing in few individuals to a large number of the populations.

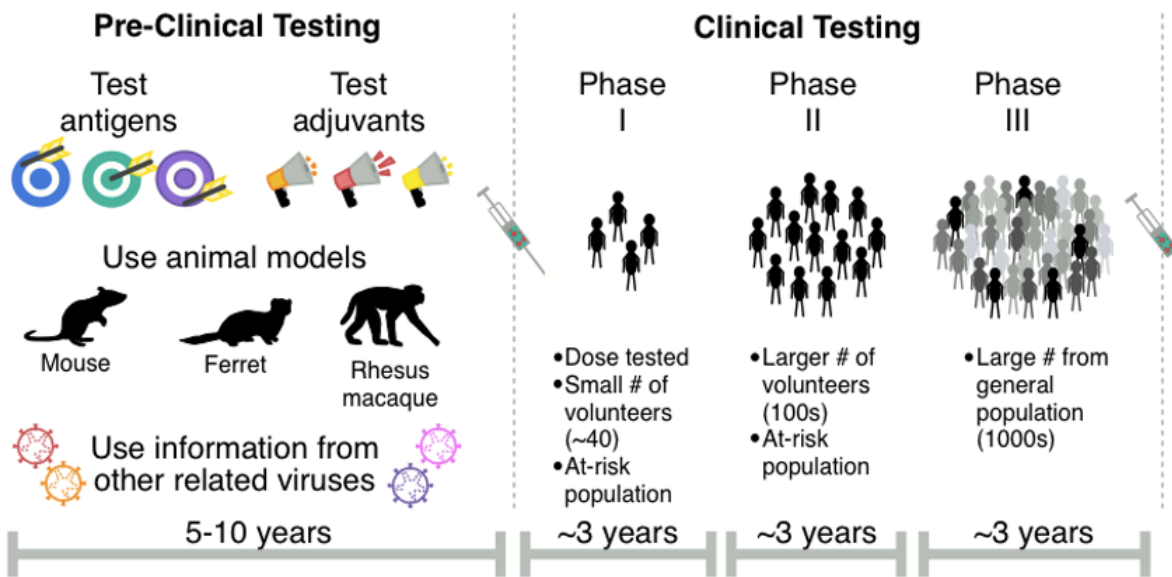


Image by: Kylie Quinn and Damian Purcell
 Figure 2: details of preclinical and clinical stages of vaccine development

In order to fast track the availability of Covid-19 vaccine, this process highlighted above has to be modified as much as possible. The current model looks at combining certain steps with the development framework as well as shortening the time period for certain processes.

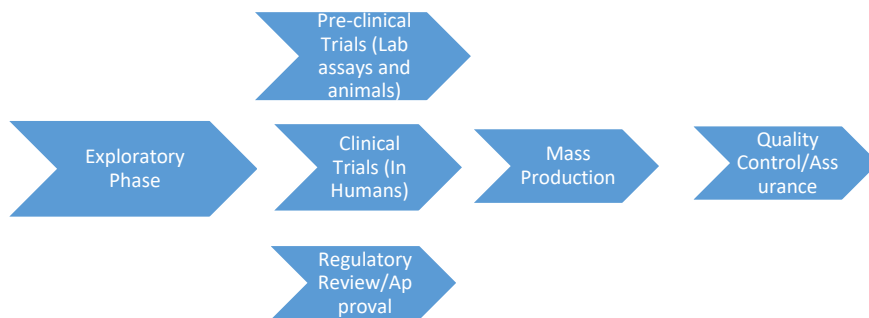


Figure 3: Development of Covid-19 vaccine model

Here scientist are modifying the existing regimens that have already undergone animal tests and shown some expected results and that they are safe. This approach poses a greater risk if not handled carefully or if not enough measures have been put in place. Fig 4 shows how this model will involve skipping past rigorous academic research but conducting this alongside the trials. This means that if academic suddenly discover new information, since testing has already commenced,

participants may have already have been adversely affected. Figure 4 shows that that the proposed model slightly staggers initiation of pre-clinical and clinical trials. Then it also proposes that the factories required to produce the vaccines should be constructed as clinical trials commences. At the end of Phase 2 of clinical trials regulatory approvals can commence such that the vaccine can be ready in 18 months.

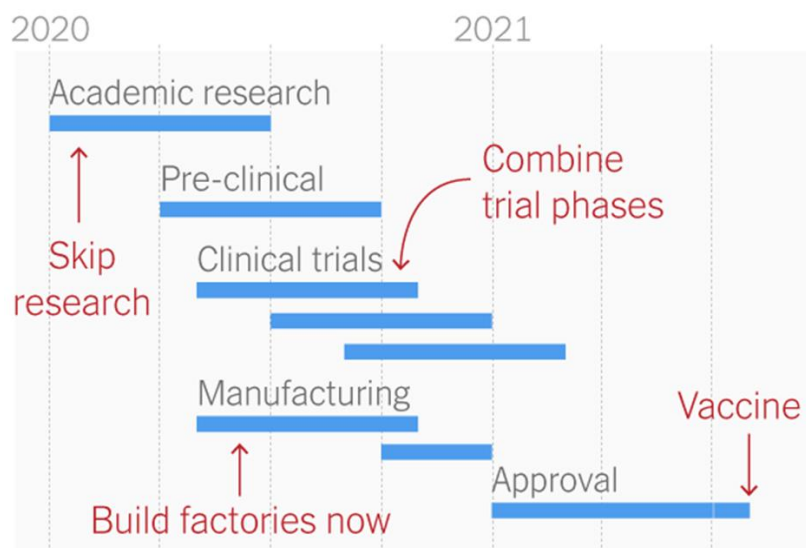


Image by Stuart A. Thompson

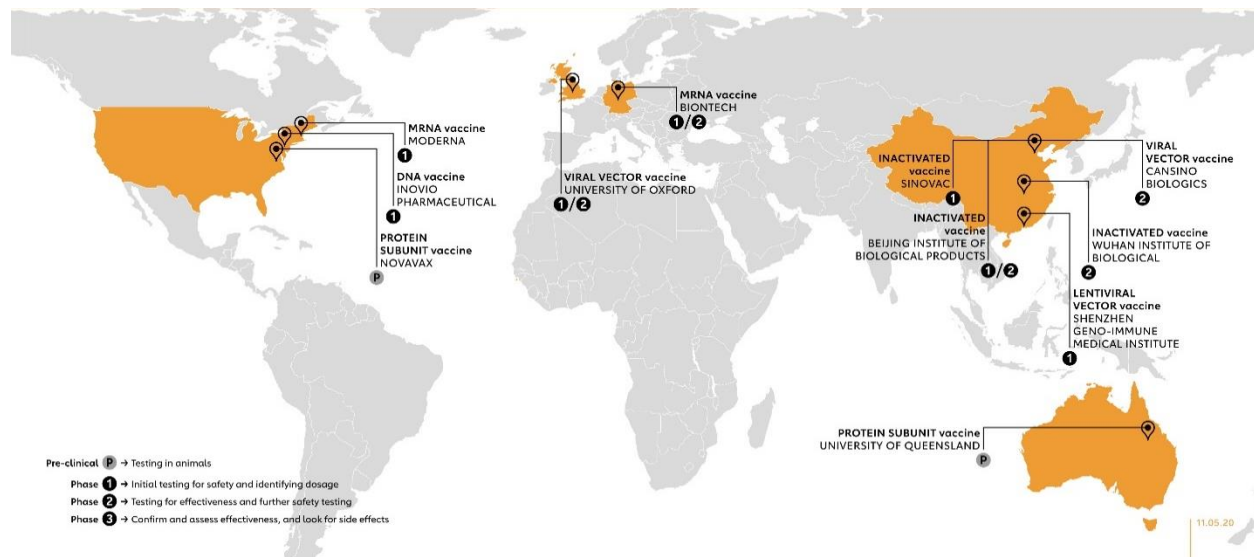
Figure 4: Express development of Covid-19 Vaccine

In Zambia all preclinical and clinical trials involving a vaccine developed using any gene manipulation require additional regulatory approval from the National Biosafety Authority (NBA). Since the development of these vaccines will be compressed regulatory authorities, such as NBA, will be responsible in ensuring that researchers and scientists come up with workable risk management and emergency plans for the protection of human beings, animals and the environment.

It is the responsibility of the regulatory authorities to ensure that the clinical trials are harmless to humans using the data from animal experiments. If and when the animal experiments show negative signs during the trial or don't seem to show any effects, regulatory authorities are mandated to terminate or halt the trial with immediate effect to minimize the risk of harming humans.

The National Biosafety Authority is well prepared to regulate the research involving 2019 SARS-Cov-2 coronavirus disease that may involve recombinant nucleic acid materials or genes. The Authority ensures effectively that all such activities adhere to national and international biosafety standards, guidelines and regulations. The Authority also has a well-established scientific Advisory Committee that gives oversight and guidance in the regulation of products of living modified organisms or indeed living modified organisms themselves. This committee comprises of professionals from scientific fraternity including life sciences, medicine, agriculture, academia as well as the community.

Now is Zambia currently participating in any of these trials? While there are over 100 products at various stages of vaccine development in the world, none of those are being developed in Zambia. Figure 5 shows that only 5 countries are conducting trials and these are the United States of America, the United Kingdom, Germany, China and Australia. Should Zambia accept to participate at any phase in the development of this vaccine or should Zambian researchers decide to research this coronavirus in trying to develop a drug or vaccine, the relevant regulatory authorities ensure that all clinical trials and research are safe and follow the national and international research standards, guidelines, and ethics. With a lot of emerging biotechnological tools, there is a greater chance that the COVID-19 vaccine will be a product of these tools and the regulatory authority responsible for biosafety and biotechnology takes responsibility to ensure the safety of humans and animals.



<https://www.gavi.org/vaccineswork/covid-19-vaccine-race>

Figure 5: Development of Covid - 19 vaccines around the world.

Reference; <https://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation>