Covid 19 was first reported in Wuhan, China in December of 2019 after a group of patients began showing pneumonia symptoms of an unknown cause. It was declared a pandemic on the 11th March 2020.By the end of 2020, three vaccines against Covid-19 have been approved. By January of 2021 all three were in circulation meaning that in 13 months, they have been tested and approved while, under normal circumstances, it takes, on average, six years leaving many to question the safety and validity of the results. If these vaccines can be made safe and tested so quickly, why can’t others?

To understand this, one must first understand the process of clinical trials, why they have been developed and what slows the process.

Currently, the clinical trials process is divided into four distinct phases. This variation of the process arose after several incidents such as the Thalidomide Scandal. It became apparent, after these events, that more regulations were needed in order to guarantee the safety of the drugs that were being used. Thalidomide is a drug that was developed in the 1950s, originally intended as a tranquiliser though was used for treating many other conditions such as the flu, nausea and morning sickness in pregnant females. While there is evidence of it passing safety tests on animals – in some cases, dosages of over 600 times the normal human dosage had no effects on rodents – there is little in the way of testing on humans. Upon being released to the wider public it became common treatment for relieving symptoms caused by pregnancy, despite never having been tested on pregnant ladies. It was not known, at the point of release, that the drug could be passed through the placenta and cause harm to the foetus. Many children, if their mother had taken thalidomide during pregnancy, were born with life altering deformities. This incident forced governments and medical authorities to review their licensing policies and as a result the way drugs were tests and inspected improved internationally. Regulatory bodies such as the FDA in the USA and the MHRA in the UK were developed after these incidents.

The four phase process currently in use is optimised to ensure the safety of the drug and it has become mandatory that all treatment is tested in humans, including the target bracket. According to the FDA, in Phase 1, the new treatment or vaccination is given to a small group of health volunteers with the aim of ensuring the new medicine is safe and to determine dosage. It is also determined here if the drug it could offer therapeutic value. Approximately 70% of drugs are successful within this phases and move onto Phase 2 where it is tested on a larger group of people – up to several hundred - which with the target disease or condition. Here, the efficiency is tested and side effects are looked for. Around 33% of drugs move onto the next phases. Phase 3 is with a much larger group of patients, a few thousand, are tested, one again looking for the efficiency but now also looking at an adverse reactions. Around 25% of treatments or vaccinations make it past his phase. At this point, regulators check the evidence collated over the years it took for this process to take place and it is determined which patients qualify for the treatment. After this the drug can be launched. However, in many cases, post-release, the drug goes through a fourth phases, with several thousand patients where the safety is once again tested and further experiments – such as how the drug interacts with other medicines, or long term effects – are also tested.

From discovering the compound to releasing, this process takes – on average - ten to fifteen years. To understand how the Covid-19 vaccine trails managed to fast track this process we must first understand what slows a general clinical trial to this extent.

These trials cost on average supersedes $1 billion. The company running the clinical trial must find some way of attaining this funding and most of the time it will be done on a phase by phase basis. This will inevitably increase time between phases, prolonging the process. Secondly, with the introduction of regulatory bodies has also increased time. As there are so many drugs in development – and each needs approval before they can be released – it leads to a very long waiting list. This can add up to nearly two years and all the time spent on this trial could be for naught if the approval is not achieved. Finally, actually recruiting enough volunteers can add years to the whole process. In an interview with Matt McCarthy he said ‘it can take years to recruit two, three hundred people into a […] study.’ These issues consequently increase the time taken for a clinical trial.

So, without interfering with the testing process it is possible to take years away from the process if the funding and volunteers are available. Then, as the Covid-19 vaccines have been, if the drug is prioritised by the regulatory body and as consequence skips the queue, even more time can be taken off. By these adjustments to the clinical trials process it seems close to half of the time taken for the trial can be taken off. However, even then, it seems a trial process would still take years.

Other things that impact the length of study is the disease being studied and what is known about it and the discovery of a compound that has potential to in some way help combat the disease. As shown in the timeline above, discovery of the compound and pre-clinical testing – including animal trials and computer run simulations– can take up to two years. Should this work already have been done, even more time can be taken from the expected average.

The question on many people’s minds is how did they develop the vaccine so quickly. It is relatively known that medicine development takes years. To examine this, I interviewed Matt McCarthy the Product Line Executive of ERT. He raised the point that a vaccine trial and a medicine trial have a very big difference. While both require volunteers there are requirements for a treatment. ‘You’ve got to find a sick person with the right disease whose willing to take part in the study that meets the criteria that there is no other treatment that would be better for them’ but a vaccine trial needs a healthy person – ‘almost anybody is eligible’. This key difference is what has made the vaccine trials move much faster than the treatment trials.

In a wider comparison, the general comradery and determination to develop a vaccine so life can return to normal, has inspired more people to volunteer than for other vaccination trials. ‘So in the time of a pandemic it can take two months to recruit 40,000 people. That’s unheard of, but the population is very aware of what’s going on.’

The first two vaccinations to come out in the UK – Pfizer and the Oxford-AstraZeneca vaccine – had something in common too. Both had work done before the pandemic even began. Professor Sarah Gilbert who worked on the Oxford Vaccine, in an interview with BBC news, said ‘We were planning how can we go really quickly to have a vaccine in someone in the shortest possible time.’ After the Ebola outbreak to which the world was slow to move and 11,000 people died it became apparent to the medical world that a plan was needed to tackle the next outbreak.

It is also important to understand that for the Oxford vaccine, they were not starting from scratch. In the last 20 years, the coronavirus has ‘tried to jump from animals to people twice’, once in 2002 and again in 2012. Due to this, it is a known virus to the medical community; scientists already knew the virus’s biology and its weak spot. This meant that it was known what they needed the vaccination to attack and working from the ChAdOx1 vaccine they had previously developed for the 2012 jump, they essentially already had the vaccine for Covid-19. All they needed was the full genetic code of the coronavirus and when Chinese scientist shared this on 11th January, they had all they needed to begin testing the vaccine.

One long standing issue in nearly all clinical trials is financing. As stated above, a Clinical Trail is incredibly expensive and this too was an issue for Covid-19 vaccine trials. However, with the world watching as it began to shut down, funding flooded in. In May 2020, the Government ‘announced £65.5 million of new funding for the vaccine being developed at the University of Oxford’. The money helped solve many problems. Production of the vaccine was moved to Italy and the overflowing funding allowed for the issue of European lockdown to be worked around.

The Oxford vaccine was approved 30th December 2020 and the first doses were released within the next week. The process was heavily expedited but the evidence gathered was ultimately approved by the regulatory bodies suggesting there was no discrepancy in its validity.