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Leading to safety: Managing risk in vaccine innovation

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17 June 2021

The speed at which the global life sciences industry developed multiple safe and effective vaccines against COVID-19 has been remarkable. **Kirsten Shastri, Life Sciences Underwriter at Beazley**, discusses the role of insurance in supporting vaccine innovation and highlights some of the common causes of claims.

Over centuries vaccines have become one of the most important public health innovations, reducing mortality rates and helping control the spread of disease. Since the 18th century when Edward Jenner discovered that inoculating someone with a small dose of cowpox provided immunity against the more lethal smallpox, vaccines have been used to help our immune systems fight viral infection by exposing our bodies to a sample of the virus, or part of its genetic code, just as it would when we are exposed to the actual disease.

While it sounds relatively straightforward, the recent development of COVID-19 vaccines, within a year of the virus' emergence, is a huge accomplishment for the life sciences industry. To reach this point, those involved will have navigated a myriad of potential pitfalls and risks, made more acute by the pressure to expedite the process and help end the pandemic. The insurance industry has played an important supporting role in this, deploying its risk management expertise to develop bespoke wordings to aid the rapid development of vaccines.

In the longer term, what has been achieved over the past year under an intense spotlight, could also transform the life sciences industry. The shortened timeframe is likely to increase consumer and investor expectations alike. Being the first to market with a successful vaccine brings huge financial and reputational gain to pharmaceutical companies. Pressure to expedite the process raises the stakes and increases pressure on those involved in drug and vaccine development to get it right the first time.

Despite what we have learned about the behaviour of viruses and immunology in the last 200 years, there is no guarantee that any project will produce an effective vaccine.

Getting a vaccine to market and ensuring it is safe and effective only comes through extensive research and

clinical trials, and thorough regulatory review. The process on average takes 10 to 12 years and the risk of failure is high. According to research by The Massachusetts Institute of Technology, in the last 20 years only 39.6% of vaccine projects have resulted in a drug being approved to go to market. Today only 26 diseases are preventable through vaccination according to the World Health Organisation[1], and many deadly infectious diseases remain for which we have no effective vaccines or treatments.

Trials and testing

For success, there are many challenges to overcome at different stages in the clinical research and trial process, which have to be navigated within strict regulatory controls.

Testing the safety and efficacy of a vaccine only comes as the result of extensive pre-human trial research; a process that can easily take two years in normal circumstances.

Before moving to human trials, the sponsor or investigator must get approval from the Medicines and Healthcare Products Regulatory Authority (MHRA) in the UK, which authorises clinical trials and approves new medicines and devices for use. They must also obtain approval from a research and ethics committee (REC), which reviews the trial protocol against a set of standards to ensure it is safe and ethical.

Failure to prove that the proposed trial meets these standards could mean revising trial protocols or starting the process over with a back-up candidate costing time and money, potentially losing first-to-market advantage.

To put things in perspective, the mumps vaccine, previously considered as the fastest to be developed, took four years, while the first COVID-19 vaccines took less than 12 months. Several factors contributed to this incredible speed, including knowledge and lessons learned from dealing with MERS and SARS as well as the use of mRNA technology (instead of using a traditionally weakened version of the live virus), which has been studied by scientists for decades, and used in cancer research to target specific cancer cells.

The rollout of multiple COVID-19 vaccines in record time driven by the collective efforts of the global life sciences community, health leaders and governments also required public reassurance to alleviate those concerns around reducing the research phase and how to mitigate the potential impact of this on human trials.

After all, information learned during research and planning forms the basis for human testing. While human trials inherently carry risk, this can be mitigated through proper trial design and ensuring that rigorous protocols are embedded for the duration of the trials, including 'learn and confirm' cycles to address any variance from anticipated results. Upholding these standards reduces the potential for human error that can lead to bodily injury and claims against those running the trial.

Risk mitigation

All vaccines that go through clinical trials, must prove safety and effectiveness with the MHRA as the body responsible for reviewing data from clinical trials and authorising vaccines, for use. The UK's MHRA was the first national regulator to provide approval for a COVID-19 vaccine thanks to adopting an agile 'rolling review' process, which means rather than waiting for the trial to be completed, and a full data set to be sent for review as would normally be done, packages of data are provided to the MHRA on an ongoing basis.

It is also important to recognise the authorisation provided is not full marketing authorisation normally provided by the MHRA. As it is only temporary, emergency use authorisation 'EUA' approved, lasting one year, the sponsor/investigator company needs to work with the MHRA to continue to provide data on safety and efficacy. Only once comprehensive data has been provided, will full marketing authorisation be granted.

Looking forward, the life sciences sector may have to balance new consumer and corporate expectations for the delivery of vaccines in the future. The industry will have to balance how to manage expectations with how it will operate when 'normality' resumes both in terms of what is reasonably possible to deliver safely and compliantly and in terms of the regulatory framework.

Robust risk management measures and having specialist insurance in place in case claims arise is important, as is having experienced brokers and underwriters who understand the pace of change

within the industry. Failure by organisations to stay up to date with the rapid changes within the life sciences sector presents not only a risk to trials' success but potentially to those taking part.

Failure to properly monitor the trial raises the potential for claims arising from bodily injury to trial subjects, and so it is a legal requirement (The Medicines for Human Use (Clinical Trials) Regulations 2004) in the UK for all clinical trials that the sponsor or investigator have insurance or indemnity in place to cover the liability of the researchers. This includes non-fault compensation for injury to volunteers before the trials go to ethics committees for review.

Similarly, claims could arise if the sponsor failed to adequately warn the participants about the risks, as providing clear information is critical to participants' decision over whether to volunteer in a research study. Problems in the running of the trial resulting in lengthy delays could bring legal action against contract research organisations (CRO) from sponsor corporations where it causes them a financial loss.

Even the best-designed trial carries risk. Organisations that understand the risks and factor risk mitigation into the design of the trials are more likely to succeed. In a high stakes sector working with insurance partners that have the experience to understand the challenges of the sector will help the continuous growth of this complex and fast-moving sector.

Sources:

1 "ESTIMATING PROBABILITIES OF SUCCESS OF VACCINE AND OTHER ANTI-INFECTIVE THERAPEUTIC DEVELOPMENT PROGRAMS", NBER Working Paper No. 27176, May 2020

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Kirsten Shastri joined Beazley as an underwriter in September of 2019 to start up the International & UK Life Sciences offering. She comes from a background in science, having studied Human Sciences at University College London and later, spent time in industry researching stem cells before joining the insurance industry 8 years ago. Kirsten writes business on a worldwide basis within the field of Life Sciences, Miscellaneous Medical and the newly launched Virtual Care product.

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