WHAT HAPPENS AFTER A COVID-19 VACCINE TRIAL SUCCEEDS?

EVERSANA™

Four Pharmacovigilance Challenges to Address During Commercialization

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By late November of 2020, more than 57 million people fell ill to COVID-19; over 1 million affected patients lost their lives; and the virus continues to surge in the United States, India, Brazil and Columbia.

As pharma companies around the world race to find a vaccine to control the spread of the virus, they are faced with the question: What happens when we succeed? How will we quickly and safely distribute the vaccine globally?

So far, there have been more than 50 COVID-19 vaccine trials, with new vaccine candidates continuing to emerge. Pressures from the World Health Organization have accelerated vaccine development and trial processes, driving us closer to an answer to the pandemic.

But what's the plan moving forward? How will pharma companies ensure a successful vaccine meets compliance regulations when their drug is ready for distribution? To do this, they'll have to achieve compliance standards in four major areas.

1 Mass Data Collection

When a successful vaccine is ready for distribution, the pharma manufacturer will have to produce at least 16 billion doses to meet global demand. That's two doses for each person in the world, as the top vaccines in trial require double doses to be effective.

And once the vaccine has been made available to the masses, the successful pharma company will be held accountable for collecting long-term safety and health data on patients. This data includes information that will help develop the safety profile of the vaccine, such as an adverse event following vaccination, medical history, COVID-19 status, age, demographic and patient medications.

Accomplishing this feat – the largest data collection in human history – will be revolutionary and require advanced, intuitive technology that can not only collect data, but manage and provide real-time, actionable insights. With next-generation artificial intelligence (AI) and machine learning (ML) platforms, the pharma company will be able to use accurate, integrated patient data to confirm that their vaccine is safe and effective and is distributed throughout patient populations.

2 Regulatory & Safety Reporting

The COVID-19 pandemic has forced global pharma companies into emergency production as they search for an effective vaccine. While standard clinical development plans span 7 to 10 years to complete, the world is pushing past this red tape.

As a result, pharma companies are working at warp speed; and when a vaccine is ready, regulatory approval times will be significantly reduced. In this unprecedented situation, it's as important as ever that the pharma company has an agile, comprehensive medical services team and integrated compliance model. Companies will need a proven pharmacovigilance plan that works with advanced data analysis platforms to access and mitigate risks, identify safety issues and provide product usage recommendations to maximize patient outcomes.

3 Patient Safety and Monitoring

There's more to compliance than data collection and risk mitigation. After the vaccine has been distributed and administered, how will the company know if a patient has adverse side effects? How will they know that patients are adhering and people are receiving the second vaccine dose?

The answer to these questions is instituting a proactive patient-focused pharmacovigilance team to pull this data from vaccinated populations. Whether it's through patient surveys or registries, the number one priority must be collecting this data and analyzing it to communicate any adverse event to patients. With an established patient-focused pharmacovigilance structure in place, the pharma company can guarantee 24/7 support for patients who have received the COVID-19 vaccine while also ensuring that patient safety data is being addressed.

Even in an emergency health situation, long-term compliance evaluation is necessary for treatment effectiveness and patient care.

4 Mass Manufacturing & Distribution

Another compliance area of concern is the rapidmass distribution of the vaccine. Historically, pharma manufacturers aim for cost efficiency when producing their drugs, but this is not a viable option due to COVID-19 time constraints.

Now the pharma company will have to produce the vaccine in the U.S. or European markets. To quickly mass-produce the vaccine, manufacturers and distributors will have to adjust their production schedules, creating a rushed cascade effect in the world of pharma.

The management of the vaccine's global distribution will take an established expert in supply-chain management with experience in urgent access programs. During this global distribution, there will be compliance complications and hurdles that will need to be overcome with scalable reverse logistics solutions, validated medical product warehousing, security protocols, and excellent inventory and control management.

The Need for a Global Integrated Model

The pharma company of this new, lifesaving vaccine will ultimately be faced with the challenge of efficiently fulfilling pharmacovigilance standards while providing the quickest means to global patient access. Meeting these market demands requires company infrastructure steeped in agility and market experience, as well as a team equipped with advanced expertise and data technologies to safely, rapidly distribute the vaccine.

Compliance challenges are a moving target across drug manufacturing and market distribution processes and standards. With integrated compliance challenges, safely distributing the COVID-19 vaccine will require an integrated commercial services model that makes compliance a priority.

While cutting-edge pharma companies focus on vaccine development, commercialization demands are right around the corner. Successfully distributing the vaccine post-production is going to take advanced understanding of regulatory requirements while compliance is monitored across pharmacovigilance, medical affairs, regulatory and quality needs.

Through a complete commercialization model, centralized compliance can be integrated within patient services, channel management, data and analytics, digital medicine and field solution services. By utilizing a larger commercial platform, pharma companies can expect 24/7 information access for patients and providers with safety and efficacy follow-up and cost-effective, long-term data analysis throughout the vaccine life cycle.

A New Reality

A global pandemic requires a global solution and approach. Partnering with a single integrated commercialization partner, like EVERSANA, allows for customized, flexible solutions for pharma companies of any size and provides solutions that will ultimately enhance COVID-19 vaccine efficiency, patient adherence and quality. Adapting to new, agile models of commercialization is the answer to quickly and safely launching the world's most sought-after vaccine and saving patient lives.

Review this COVID-19 Safety Briefing for a detailed look at concerns surrounding the new COVID-19 vaccine and solutions to a safe, efficient global launch.