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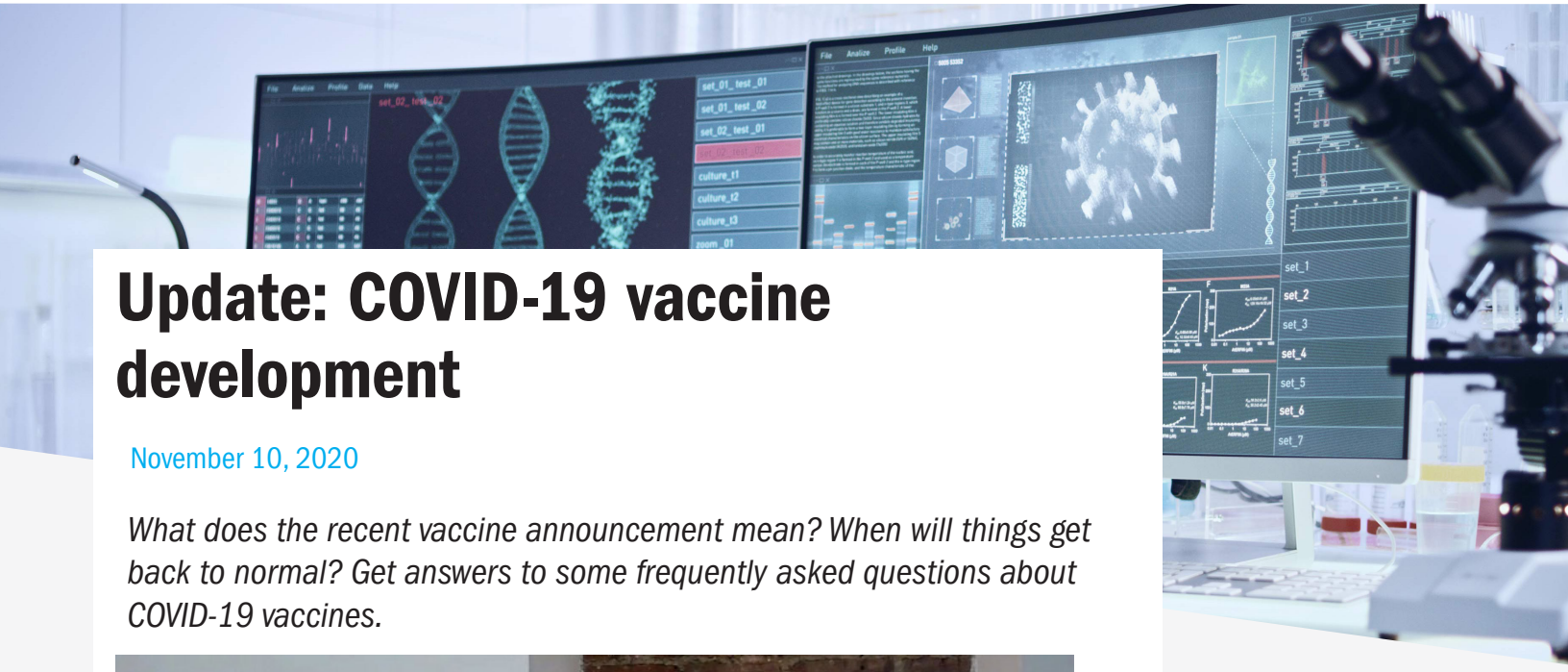

Update: COVID-19 vaccine development

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What does the recent vaccine announcement mean? When will things get back to normal? Get answers to some frequently asked questions about COVID-19 vaccines.

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Q: How many vaccines are currently in development?

A: There are over 180 vaccines in development for COVID-19. Normally, other diseases would have a dozen or so concurrent therapies being developed — but this is an unprecedented disease, so the options are more than ten-fold the norm. It's also the fastest a vaccine has ever been developed from start to finish (could be as fast as nine months). Prior to COVID, the fastest vaccine took about four years to develop. If this schedule holds up, the first emergency-use limited-approval could come by the end of 2020, and a broader approval could come in the first half of 2021. However, it's all contingent on what the final clinic data looks like, which is the Phase III data.

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Q: What can we expect following Phase III clinical trials?

If the Phase III data from one or more vaccines is positive, suggesting that one of the vaccines works, the manufacturer will work with the FDA to submit all of their data on human patients who have received the vaccine, as well as accompanying animal and manufacturing data. The intent is for the FDA to confirm the results and better understand whether the vaccine meets the minimum threshold of reducing the risk of getting the virus. Also, the FDA must ensure that the vaccine is safe and in line with other vaccines that have been approved for other viruses.

The great thing about having multiple vaccines in development that use different technologies and are developed by different companies is that it increases our chances of getting at least one vaccine to market.

Q: What does the Pfizer/BioNTech vaccine announcement mean?

A: Pfizer and BioNTech announced that their vaccine is over 90% effective, meaning that people who are vaccinated with their treatment have a 90% lower chance of getting COVID-19. This is well ahead of what many analysts had been expecting. As a basis of comparison, the flu vaccine is only about 40% to 50% effective. The very positive data means that we may have the vaccine available to the general public sooner, and, as long as the safety data looks good, we may also see more people take the vaccine. We still need to see full data to know what side effects were seen.

Q: How long will approval take after Phase III data is submitted to the FDA?

Generally, the FDA promises to return their results in as short as eight months after the submission of data. But for COVID-19, we're working on accelerated timelines because of the virus's impact globally. So, we can expect as short as a one-month turnaround time from the Phase III data read-out to the emergency use authorization (EUA). EUA is intended for only a limited set of individuals: healthcare workers, frontline workers and people with immunocompromising conditions. These individuals have a higher risk of getting COVID-19, so it's worth it for them to potentially get the vaccine sooner than the broader population. People who have a decreased risk can wait for additional evidence supporting the vaccine being safe and efficacious. The broader population should receive the vaccine as early as the first half of 2021. Between now and that time, we'll be able to collect a lot more safety information to know exactly which patients should and shouldn't receive the vaccine based on the data.

Q: Will there be sufficient supply of the vaccine for everyone?

A: After a vaccine is approved by a regulatory body, there's a question of supply. Most drug companies in the lead for developing a vaccine are expecting to be able to produce about a billion doses by the end of 2021. And most countries have already contracted with leading developers to procure supply for their citizens. Assuming there's multiple vaccines approved, there should be ample supply in 2021 for most countries — and people who aren't vaccinated in 2021 should be able to get it shortly after.

The key is to stay patient and continue to watch each of these Phase III clinical data sets to learn what the various vaccine profiles look like including how safe and efficacious they are and what vaccine options will become available to us.

Q: How long will it take for enough people to be vaccinated to achieve herd immunity?

A: Some people may have safety concerns and may not be comfortable taking the vaccine immediately after approval or at all. We'll only know whether those concerns are legitimate once we see the Phase III data over the next few months. Recent consumer surveys suggest that over 50% of people are willing to take the vaccine before even seeing the clinical data, and we only need about 70% of people to either gain immunity from the vaccine or recover from the disease to reach herd immunity. Our expectation is that by the end of 2021, at least 50% of the U.S. and major markets will get the vaccine — if not more.

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