

## Discover & Deliver: Timelines for Leading Vaccine Candidates Show Safety and Effectiveness Are Top Priority

# 44 Vaccines

in the clinical stages of development



# 154 Vaccine Candidates

in the pre-clinical stage

Source: WHO

Earlier today, a little-known [Food and Drug Administration committee met](#) to discuss developments related to a COVID-19 vaccine. The meeting of the Vaccine and Related

Biological Products Advisory Committee is particularly timely, as two companies enter the home stretch of the race to develop an immunization against COVID-19.

In the last week, both Pfizer and Moderna released an updated timeline for their Phase 3 clinical trials, based on their ability to meet three key criteria:

**Efficacy:** Both trials need to demonstrate a certain number of COVID-19 cases occurred to illustrate the vaccine is more effective than the placebo. [Pfizer estimates](#) they will reach this threshold by the end of October. Moderna expects this will occur sometime in November.

**Safety:** The Food and Drug Administration (FDA) requires companies provide two months of safety data following the final dose of the vaccine. Pfizer estimates the trial will surpass this milestone the third week of November. Similarly, Moderna projects they will have sufficient safety data by the end of November, but they caution the FDA may not issue a decision on the application until December.

**Manufacturing quality & consistency:** Finally, if the vaccine candidate is deemed effective and safe, the company must provide manufacturing data to demonstrate the vaccine can be produced with consistency and quality. Pfizer has ramped up its manufacturing capacity in parallel with the clinical trial. Pfizer estimates they will have the data ready for submission prior to surpassing the safety milestone.

While some may lament the science isn't moving fast enough, Pfizer's CEO noted the company can only move as fast as the *speed of science* allows.

Both companies' timelines to develop a vaccine at warp speed reaffirms what we already knew: the business community continues to lead the way in the fight against COVID-19.

—Kelly Anderson, Director of International Policy, Global Innovation Policy Center