

COVID-19 Vaccine Maker Pledge

We, the undersigned biopharmaceutical companies, want to make clear our ongoing commitment to developing and testing potential vaccines for COVID-19 in accordance with high ethical standards and sound scientific principles.

The safety and efficacy of vaccines, including any potential vaccine for COVID-19, is reviewed and determined by expert regulatory agencies around the world, such as the United States Food and Drug Administration (FDA). The FDA has established clear guidance for the development of COVID-19 vaccines and clear criteria for their potential authorization or approval in the US. The FDA's guidance and criteria are based on the scientific and medical principles necessary to clearly demonstrate the safety and efficacy of potential COVID-19 vaccines. More specifically, the agency requires that scientific evidence for regulatory approval must come from large, high-quality clinical trials that are randomized and observer-blinded, with an expectation of appropriately designed studies with significant numbers of participants across diverse populations.

Following guidance from expert regulatory authorities such as the FDA regarding the development of COVID-19 vaccines, consistent with existing standards and practices, and in the interest of public health, we pledge to:

Always make the safety and well-being of vaccinated individuals our top priority.

Continue to adhere to high scientific and ethical standards regarding the conduct of clinical trials and the rigor of manufacturing processes.

Only submit for approval or emergency use authorization after demonstrating safety and efficacy through a Phase 3 clinical study that is designed and conducted to meet requirements of expert regulatory authorities such as the FDA.

Work to ensure a sufficient supply and range of vaccine options, including those suitable for global access.

We believe this pledge will help ensure public confidence in the rigorous scientific and regulatory process by which COVID-19 vaccines are evaluated and may ultimately be approved.

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