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## Vaccine Development at Warp Speed: R&D Preparedness Research, Clinical Trials and Regulatory Review, and Vaccine Equity for Potentially Pandemic Pathogens

The West Africa Ebola pandemic of 2014-2015 and the pandemic of COVID-19 have forever changed the course of research and development of medical countermeasures for pandemic diseases and the timeline for delivering effective drugs, vaccines, and diagnostics. Many lessons learned have been applied more rapidly than ever before, and many lessons have remained unaddressed. The issue is not can we do better, but because we must do better what are the barriers and how do we move beyond them. It is clear that preparatory research is a starting point. We must be able to better assess and predict future threats, invest in research to understand the biology of such pathogens with pandemic potential, identify targets for interventions and diagnostics, and develop platform technologies that are rapidly adaptable to the specific microbial threats that emerge. Greater efficiency in the way the multiple steps in product development are solved and aligned with more nimble regulatory mechanisms in a manner that does not sacrifice safety is essential. Planning for clinical research and clinical trials must also antedate the next pandemic, be functional and ready to target any new outbreak and address the added challenges of an uncontrolled emergency with high transmission, substantial morbidity and mortality, and limited ability to control the outbreak in its early stages. Finally, because ongoing transmission of these diseases anywhere represents a threat to populations everywhere, achieving equity of access to countermeasures across the world that are affordable and accessible is essential, including investments in greater future R&D equity among high-, middle-, and low-income countries. These challenges will be discussed using vaccines as an example in the context of emerging technologies in basic and translational research, product development, and successfully implementing vaccine delivery programs.