Validating full safety of vaccines might take months but effectiveness judgements likely soon

The global campaign to identify effective vaccines against COVID-19 has entered the final stage of testing for regulatory approval—Phase III trials—for several promising candidates. Evaluation will be guided by criteria established by the Food and Drug Administration and the World Health Organization.

The minimum threshold for efficacy is observed reduction of disease incidence of at least 50 percent, with high statistical confidence of efficacy above a minimum of 30 percent. Full safety reviews of the vaccine candidates may take several months, to ensure any adverse events are given sufficient time to become evident and then studied.

For efficacy, however, statistically valid determinations can be made after approximately 150 confirmed cases of COVID-19 among trial participants, which may occur relatively quickly given the prevalence of the virus in many communities. Consequently, on the question of whether a vaccine works to prevent progression from the virus to the disease, a clear signal is likely to occur in a few months after the trial begins rather than over the longer time frames that may be necessary for evaluation of their safety profiles.

Read the full report here (PDF)