Vaccine Development Process

HOW DO WE KNOW IT’S SAFE AND EFFECTIVE?

1. SAFETY CHECKS
   A COVID-19 vaccine needs to pass all the same safety requirements as a typical vaccine. After a safety review by FDA at the initial checkpoint determines no issues, each COVID-19 vaccine is allowed to be studied in humans for the first time in a Phase I trial.

2. CLINICAL TRIALS
   The large number of volunteers in each COVID-19 vaccine phase III study made it easier to identify possible side effects and assess how well the vaccine prevents COVID-19.

   - Phase I: 20 to 100 people
   - Phase II: Hundreds of people
   - Phase III: Tens of thousands of people

   In the first two vaccine applications (from Pfizer and Moderna), Phase III included 30,000+ people (thirty times the amount shown) and 30% to 40% of volunteers are from racial and ethnic minorities.

3. MONITORING
   The FDA monitors for long-term effects and safety of a vaccine during and after its distribution.

*During the pandemic, COVID-19 vaccines may be authorized by FDA for public use under an emergency use authorization process or via full licensure.