Developing, Manufacturing and Distributing a COVID-19 Vaccine

Multiple COVID-19 vaccines are being developed. Thousands of people have volunteered as part of research trials to see if a vaccine prevents COVID illness and to learn more about its safety in these overlapping steps. Promising vaccines are being manufactured at the same time they are being tested, so there will be an initial supply ready to go right away when the science shows which vaccines are found to be safe and effective. Once we have a vaccine or vaccines, it will still be some time before it is widely available to everyone. States will receive limited supplies at the start. North Carolina is drawing upon the experience and expertise of leaders from historically marginalized communities to develop and implement its vaccine distribution plan.

PHASE 1 & 2:

Safety & Dosing

10s-100s of healthy volunteers

- Are there any side effects? How many volunteers experience side effects?
- What is the best vaccine dose to create an immune response with the fewest tolerable side effects?

PHASE 2 & 3:

Safety & Efficacy

>30,000 of volunteers

- Does the vaccine prevent COVID-19 infection?
- What are the most common side effects?
- Do the benefits of the vaccine outweigh the risks?

Approval & Distribution

- FDA reviews the safety and efficacy data to determine if benefits are greater than risks
- An independent, non-FDA scientific committee reviews findings
- Vaccine is authorized and recommended for use (may only be for certain populations)
- Vaccine is labeled for use, benefits, side effects

Manufacturing Preparation: Manufacturing development, scaling up, quality-control testing

Large-Scale Manufacturing: Making millions of vaccine doses for nationwide distribution, continued quality-control testing of vaccine batches and manufacturing facilities, FDA and CDC continually monitor vaccinated patients for safety

Availability: Limited availability in the beginning. More widely available over time.