Why is this COVID-19 vaccine development timeline so condensed compared to when other vaccines are licensed?

Some of the approaches that are being employed to shorten the timeline ***without sacrificing quality and safety*** include:

- Utilizing existing technology – many of the methods for producing a COVID-19 vaccine were previously being developed and explored for other vaccines.

- Developing vaccines immediately after viral genome sequence is available.

- Financing – The federal government has provided financing for COVID-19 vaccine development.

- Manufacturing – While completing the large phase III clinical trials, manufacturers can begin producing the vaccine, so that if it is shown to be safe and effective, they will have large numbers of doses ready. This is not typical because if the vaccine does not work, the manufacturer will have spent a significant amount of money to produce something that needs to be thrown away.

- Support efforts – While waiting for a vaccine to be ready, many other aspects of vaccine delivery can be prepared, including:

    1. Developing plans for how to distribute the first, limited quantities that will be available
    2. Ensuring adequate supplies for distributing and administering vaccine, like vaccine vials, syringes and other equipment needed to vaccinate
    3. Establishing mechanisms for distribution to large subsets of the population

The development and production of a COVID-19 vaccine has been called "Operation Warp Speed", does this mean shortcuts have been taken?

Operation Warp Speed is a partnership between the U.S. Department of Health and Human Services, the U.S. Department of Defense, and the private sector. The goal of Operation Warp Speed is to accelerate the development, manufacturing, and distribution of COVID-19 vaccine.

The Food and Drug Administration (FDA) has a well outlined regulatory process that assures any licensed vaccine has gone through a rigorous process to assure that it meets a standard for safety and efficacy before being released. All COVID-19 vaccine candidates being studied in the U.S. are in the process of completing these rigorous studies with no compromises in the process.

What has been significantly shortened (i.e. the "warp speed") is the production process. The federal government has decided to fund the production of the leading vaccine candidates at the same time they are undergoing studies to assure their safety and efficacy. Should the vaccine candidate meet the FDA's safety and efficacy requirements, supplies would then be ready to start immunizing right away.

What is the current safety and efficacy of COVID-19 vaccines in clinical trials?
Pfizer and Moderna have both indicated that preliminary data analysis showed that their COVID-19 vaccines are safe and effective. Pfizer reported 95% efficacy, while Moderna reported 94.5% efficacy. Preliminary data on the safety of the vaccines has also been released. Pfizer's COVID-19 vaccine showed no serious safety concerns, and there were no serious adverse events report for Moderna's COVID-19 vaccine. Preliminary data for Pfizer and Moderna are available online.

Full information regarding the safety and efficacy (performance) of COVID-19 vaccines in clinical trials has not yet been released. Information from clinical trials will be available before these vaccines are used.

How does the size of COVID-19 vaccine clinical trials compare to clinical trials for other vaccines routinely used in the United States?
According to an article published in *Human Vaccines and Immunotherapeutics* in 2012, phase III clinical trials for vaccines currently being used in the United States included, on average, 29,844 participants. Ongoing phase III clinical trials for COVID-19 vaccine include or plan to include at least 30,000 participants.

What will be needed to license a COVID-19 vaccine in the United States?
Vaccine manufacturers must follow guidance provided by the FDA while developing any COVID-19 vaccine. This includes requirements to share information about how they determined that a vaccine is safe and effective. They will need to provide data for review and information, so the FDA and other scientists can understand how the studies were designed, how many people were evaluated, and how the testing to obtain the data was done. It is likely that at first, COVID-19 vaccine(s) will not be fully licensed but will receive emergency use authorization.

How will safety of the COVID-19 vaccine be monitored?
COVID-19 vaccine safety will continue to be monitored after it is made available to the public

Can a COVID-19 vaccine cause COVID-19?
No. None of the vaccines currently in development in the United States use the live virus that causes COVID-19. Vaccination with COVID-19 vaccine could cause side effects, such as fever and body aches. These symptoms are normal after vaccination and are a sign the body is building immunity.

If you would like to see the full FQA from the North Dakota State Health Department click here