Large scale Phase III clinical trials of 30,000 volunteers allowing for rapid collection and earlier analysis of safety and efficacy data of demographically diverse populations by the FDA, reducing the typical 12-month approval process to three months.

Two promising candidates began Phase III clinical trials in July, with others to follow quickly in coming months. Before beginning Phase III, candidates must show safety data from animal and human studies.

The U.S. Government funding at-risk, large-scale manufacturing of the most promising vaccine candidates during Phase III clinical trials to ensure any vaccine proven to be safe and effective is available immediately upon FDA Emergency Use Authorization (EUA) approval or licensure.

Creating vaccine candidates immediately after viral genome sequence is available.

Using vaccine platforms developed for other diseases.

A tiered approach based on CDC recommended allocation methodology used as part of pandemic flu planning and the COVID-19 response will be used to determine vaccine distribution.

Planning for infrastructure and distribution before the vaccines are approved or authorized.

CDC leading distribution planning with DoD augmentation.

Providing continuous safety and efficacy data collected in large Phase III clinical trials.

A typical 8-month process is accelerated by:
- Creating vaccine candidates immediately after viral genome sequence is available.
- Using vaccine platforms developed for other diseases.

A typical 42-month process is accelerated by:
- Large scale Phase III clinical trials of 30,000 volunteers allowing for rapid collection and earlier analysis of safety and efficacy data of demographically diverse populations by the FDA, reducing the typical 12-month approval process to three months.
- Two promising candidates began Phase III clinical trials in July, with others to follow quickly in coming months. Before beginning Phase III, candidates must show safety data from animal and human studies.
- The U.S. Government funding at-risk, large-scale manufacturing of the most promising vaccine candidates during Phase III clinical trials to ensure any vaccine proven to be safe and effective is available immediately upon FDA Emergency Use Authorization (EUA) approval or licensure.

A typical 6-month process is accelerated by:
- A tiered approach based on CDC recommended allocation methodology used as part of pandemic flu planning and the COVID-19 response will be used to determine vaccine distribution.

A typical 15-month process is accelerated by:
- Planning for infrastructure and distribution before the vaccines are approved or authorized.
- CDC leading distribution planning with DoD augmentation.

A typical 12-month FDA review for EUA approval or licensure is accelerated by:
- Providing continuous safety and efficacy data collected in large Phase III clinical trials.

**OPERATION WARP SPEED**

**ACCELERATED VACCINE PROCESS**

**MISSION:** Deliver 300 million doses of safe and effective vaccine by 1 January 2021.