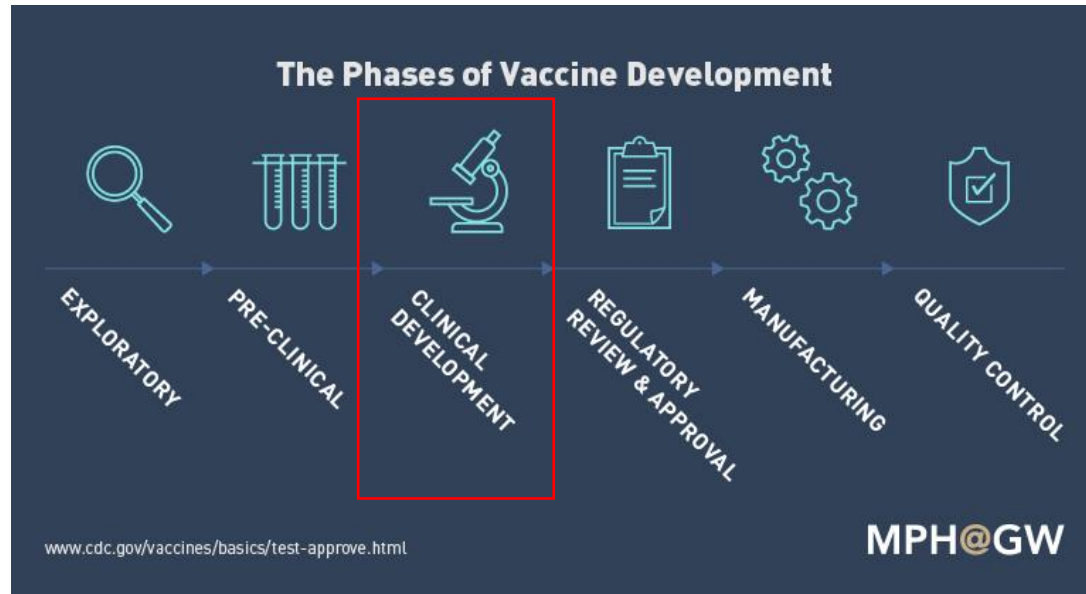


Sevens Report Alpha Webinar: **How Realistic are Vaccine Hopes?**

Thursday, July 23rd, 2020

Tom Essaye, President Sevens Report Research

Where are we in the vaccine process?



Exploratory: This research-intensive phase of the vaccine development process is designed to identify "natural or synthetic antigens that might help prevent or treat a disease." Antigens might include weakened strains of a particular virus.

Pre-clinical: During this phase, researchers — usually in private industry — use tissue-culture or cell-culture systems and animal testing to determine whether the candidate vaccine will produce immunity. Many candidate vaccines don't move on to the next stage of development because they fail to produce that immunity or prove harmful to test subjects.

Clinical development: At this point, a sponsor, usually a private company, submits an application for an Investigational New Drug (IND) to the U.S. Food and Drug Administration (FDA). This summarizes findings to date and describes how the drug will be tested and created. An institution that will host the clinical trial holds a review board for approval of the application. The FDA has 30 days to approve the application. Once the proposal has been approved, the vaccine must pass three trial stages of human testing:

- **Phase I** administers the candidate vaccine to a small group (less than 100 people) with the goal of determining whether the candidate vaccine is safe and to learn more about the responses it provokes among test subjects.
- **Phase II**, which includes hundreds of human test subjects, aims to deliver more information about safety, immunogenicity, immunization schedule and dose size.
- **Phase III**, which can include thousands or tens of thousands of test subjects, continues to measure the safety (rare side effects sometimes don't appear in smaller groups) and effectiveness of the candidate vaccine.

Regulatory review and approval: If a vaccine passes through all three phases of clinical development, the vaccine developer submits a Biologics License Application (BLA) to the FDA.

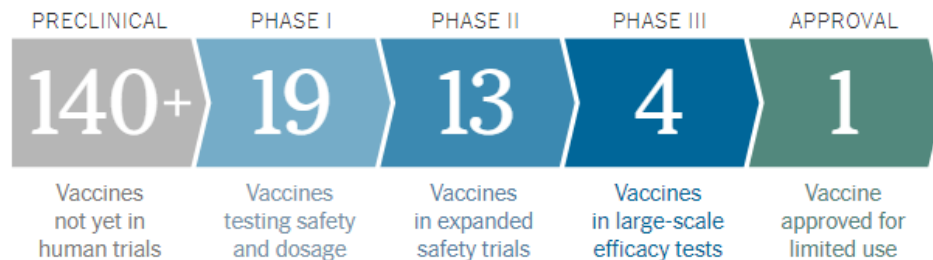
Manufacturing: Major drug manufacturers provide the infrastructure, personnel and equipment necessary to create mass quantities of vaccines. They also reap the profits of successful or widely distributed drugs.

Quality control: The approval and distribution is far from the end of the line. Stakeholders must adhere to procedures that allow them to track whether a vaccine is performing as anticipated. Multiple systems — including Phase IV trials (optional studies that can be conducted following the release of a vaccine), the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink — are designed to monitor the performance, safety and effectiveness of an approved vaccine.

Where are we in the vaccine process?

Coronavirus Vaccine Tracker

By Jonathan Corum, Denise Grady, Sui-Lee Wee and Carl Zimmer Updated July 22, 2020



Researchers around the world are developing [more than 165 vaccines](#) against the coronavirus, and **27 vaccines** are in human trials. Vaccines typically require years of research and testing before reaching the clinic, but scientists are racing to produce a [safe and effective vaccine](#) by next year.

- <https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html>

Who are the legitimate vaccine candidates in the market today?

Company	Symbol	Current Phase	Next News Date (Approximate)	Hopeful Vaccine
Moderna	MRNA	Phase 3	Q3	End 2020
Johnson & Johnson	JNJ	Phase 1	Q3	
Pfizer	PFE	Phase 2	Q3	End 2020
AstraZeneca	AZN	Phase 3	Q3	October 2020
GlaxoSmithKline	GSK			
Novavax	NVAX	Phase 1/2	Q3	Q1 2021
Inovio Pharma	INO	Phase 2	Q3	

Who are the legitimate vaccine candidates in the market today?

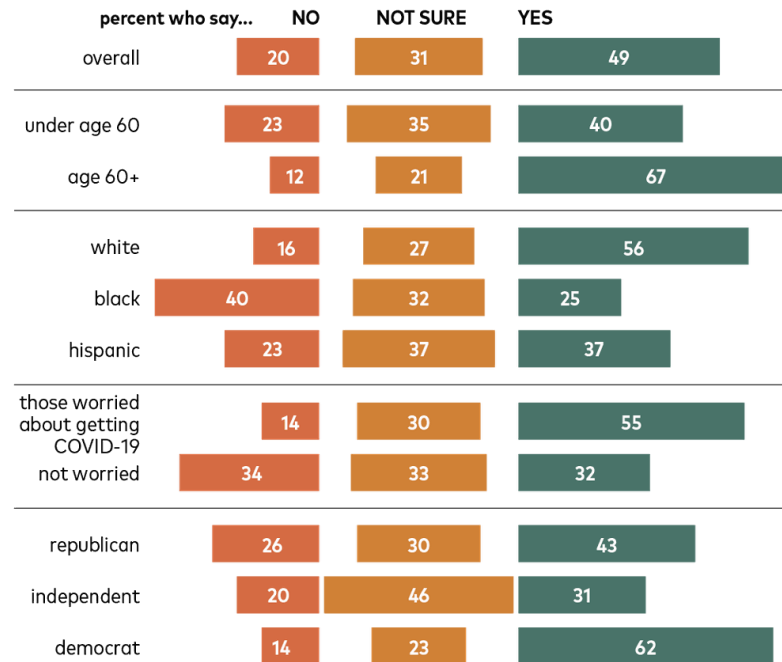
- The companies on the previous slide represent the best U.S. listed vaccine candidates.
- There are numerous international efforts underway including:
 - Imperial College London
 - Osaka University
 - Duke NUS Medical School (Singapore)
 - Koreas
 - China
- In total, there are 27 vaccines in human trials.
- Plus 140 vaccine candidates not yet in human trials.

What is Operation “Warp Speed” and why does it matter?

- “Warp Speed” is Trump Administration’s name for the program that hopefully will accelerate a COVID 19 vaccine.
- Specific goal of 300 million COVID 19 doses for the U.S. by early 2021. Effectively enough for the U.S. population
- Combinations of phases (normally one at a time)
- Five biotech firms awarded government money:
 - **AZN/PFE/MRK/JNJ/MRNA**
- More than 4 billion in awards already to those five firms and Novavax
- Why This Matters: The five finalists have a large financial backing going forward.

How effective can we expect an eventual vaccine to be for COVID 19, and can it spark a bull market?

Do you plan to get vaccinated against coronavirus?



Source: AP-NORC Poll, May 14-18, 2020



- Associated Press-NORC Center for Public Affairs Research found that just 49% of Americans would get vaccinated if a COVID 19 vaccine became available.
- Herd immunity for a virus is usually achieved with 70% - 90% vaccinated.