

COVID-19 Vaccines

Pipeline Update

14 December 2020

Who's Who?

US Effort

Operation Warp Speed (OWS): USG body responsible for strategic approach, coordination and resource allocation

ACTIV: NIH established public-private partnership for coordinating COVID-19 response

COVPN: NIH funded networks being utilized for COVID-19 Phase 3 trial design and execution



Global Effort

ACT-A: Global collaboration to accelerate development, production and equitable access to new diagnostics, therapeutics and vaccines

- **Vaccines**: COVAX Facility (GAVI, CEPI, WHO)
- **Diagnostics**: FIND, Global Fund
- **Treatment**: Unitaid, Wellcome Trust
- **Health Systems Strengthening**: World Bank, Global Fund

CEPI: Global partnership to accelerate development of vaccines against emerging infectious diseases and enable equitable access

GAVI: Global vaccine alliance with goal of creating equal access to new and underused vaccines

CONCVACT: Africa Centres for Disease Control and Prevention Consortium for COVID-19 Vaccine Clinical Trials

COVID Vaccine Pipeline

Sanofi*	J&J*	Pfizer	Moderna*	AZ/ Oxford*	Novavax*	Inovio	Merck	Clover Bio- pharm	U. of Queens- land	CureVac	U of Hong Kong
France	USA	USA	USA	UK	USA	USA	USA/ Austria	China	Australia	German y	China
<i>DNA</i>	<i>Viral Vector</i>	<i>mRNA</i>	<i>mRNA</i>	<i>Viral Vector</i>	<i>Protein</i>	<i>DNA</i>	<i>Viral Vector</i>	<i>Protein</i>	<i>Protein</i>	<i>mRNA</i>	<i>Viral Vector</i>
Ph 1	Ph 3	Ph 2/3 <i>Initial EUAs granted</i>	Ph 3 <i>Pending EUA review</i>	Ph 3 <i>Start 9/2020</i>	Ph 2 <i>Start 8/2020</i>	Ph1	Pre- Clinical	Ph1	Ph1 <i>Program halted in 12/2020</i>	PH1	Pre- Clinical
US: 2.1B	US 1.45B	US 1.9B	US 2.48B	US 1.2B CEPI 750M EU 923M	US 1.6B CEPI 388M	US 83M CEPI 17.3M EU 5M	US 38M	CEPI 3.5M	CEPI 10.6M	CEPI 8.3M EU 421M	CEPI 620K

Overlapping USG and COVAX investments

USG Funding

**Operation Warp Speed Finalist*

COVAX Portfolio

An Unprecedented Timeline

Chinese researchers reveal draft genome of virus implicated in Wuhan pneumonia outbreak

By Jon Cohen | Jan. 11, 2020, 3:00 PM

SARS-CoV-2 Sequenced

Biotech

AstraZeneca's COVID-19 vaccine enters phase 2/3 clinical trial

by Nick Paul Taylor | May 22, 2020 8:25am

First Phase 3 Testing Begins

First Sars-CoV-2 Clinical Trial Begins

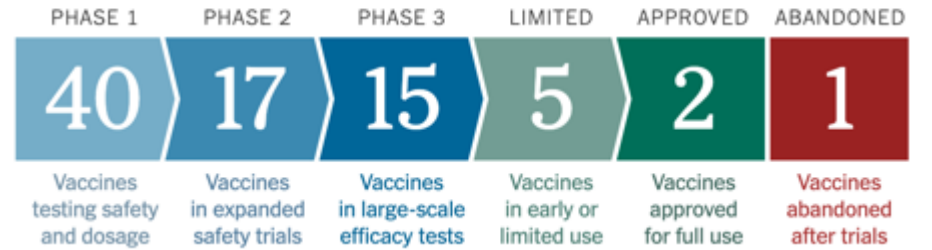
New Pfizer Results: Coronavirus Vaccine Is Safe and 95% Effective

The company said it planned to apply for emergency approval from the Food and Drug Administration "within days."

First Efficacy Data Released

Coronavirus Vaccine Tracker

By Carl Zimmer, Jonathan Corum and Sui-Lee Wee Updated Dec. 13, 2020



Vaccine Platform Refresher

DNA-based vaccines work by inserting synthetic DNA of viral gene(s) into small DNA molecules (called plasmids). Cells take in the DNA plasmids and follow their instructions to build viral proteins, which are recognized by the immune system, and prepare it to respond to disease exposure



RNA vaccines introduce an mRNA sequence coded for a disease-specific antigen. Once this antigen is reproduced within the body, it is recognized and triggers an immune response



Inactivated vaccines consist of the whole virus, which has been killed with heat or chemicals so it can't cause illness.



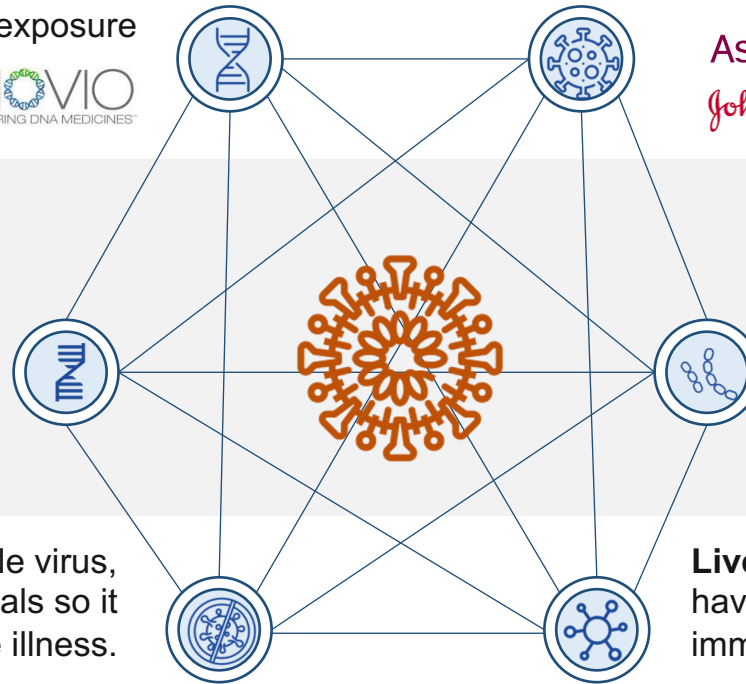
Viral vector vaccines insert a gene for a viral protein into another, harmless virus (replicating or non-replicating), which delivers the viral protein to the vaccine recipient, triggering an immune response.



Subunit vaccines introduce a fragment of the virus into the body. This fragment is enough to be recognized by the immune response and stimulate immunity.

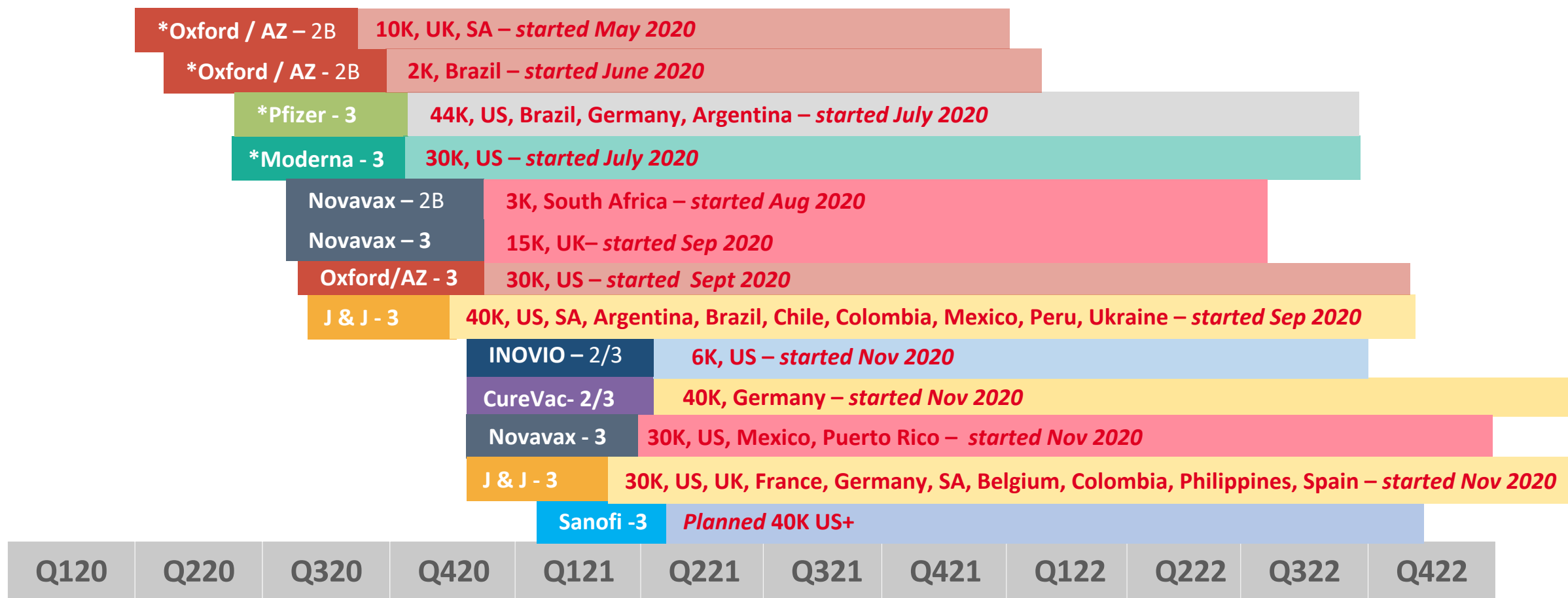


Live attenuated vaccines are made up of whole viruses that have weakened in a lab. They tend to elicit a stronger immune response than inactivated vaccines.



The Race to Efficacy Data

Experts estimate that in each trial, ~150 infections will be required to demonstrate 60% efficacy with statistical significance. Speed of enrollment and rate of infection will determine when efficacy data will be available



Bold color is proposed enrollment period; shaded color is estimated follow-up period

*Interim or final analysis displaying efficacy has been concluded

Pipeline Highlights



The UK, Bahrain, Canada, Kuwait and Mexico granted emergency use authorization to the Pfizer-BioNTech vaccine, with Saudi Arabia granting full approval. On December 11th, the FDA approved the vaccine for emergency use in the US and inoculations are set to begin within days. The vaccine is also pending regulatory review in India.



Moderna applied to the FDA and the European Medicines Agency for emergency authorization of its coronavirus vaccine on November 30th and December 1st, respectively. The company will also begin testing its vaccine in 12 to 17-year-olds this month in a 3000-person phase 2/3 trial in the US.

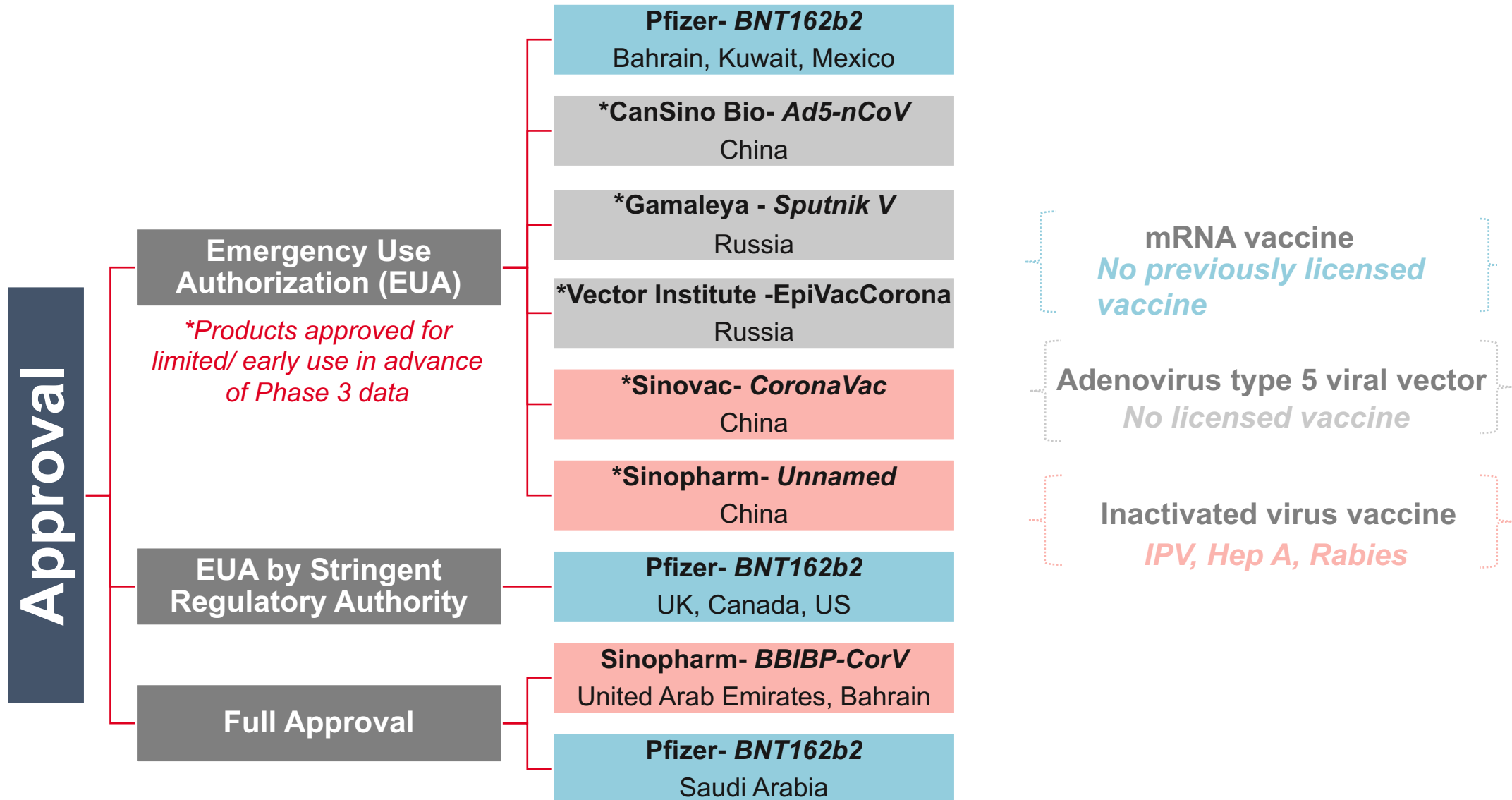


Full results published on December 8th in the Lancet reveal that AstraZeneca and University of Oxford's vaccine is safe and 70% effective in preventing infection, with efficacy ranging from 62% to 90% based on dose. The Serum Institute has applied for emergency use authorization of the AZD1222 vaccine in India.



- UAE & Bahrain approved Sinopharm/Beijing Institute of Biological Products inactivated vaccine
- Sanofi-GSK vaccine delayed till late 2021 after early-phase data revealed reduced immunogenicity in older adults
- Clinical development of University of Queensland candidate abandoned following false-positive HIV results in some participants

COVID Authorization Approval Status

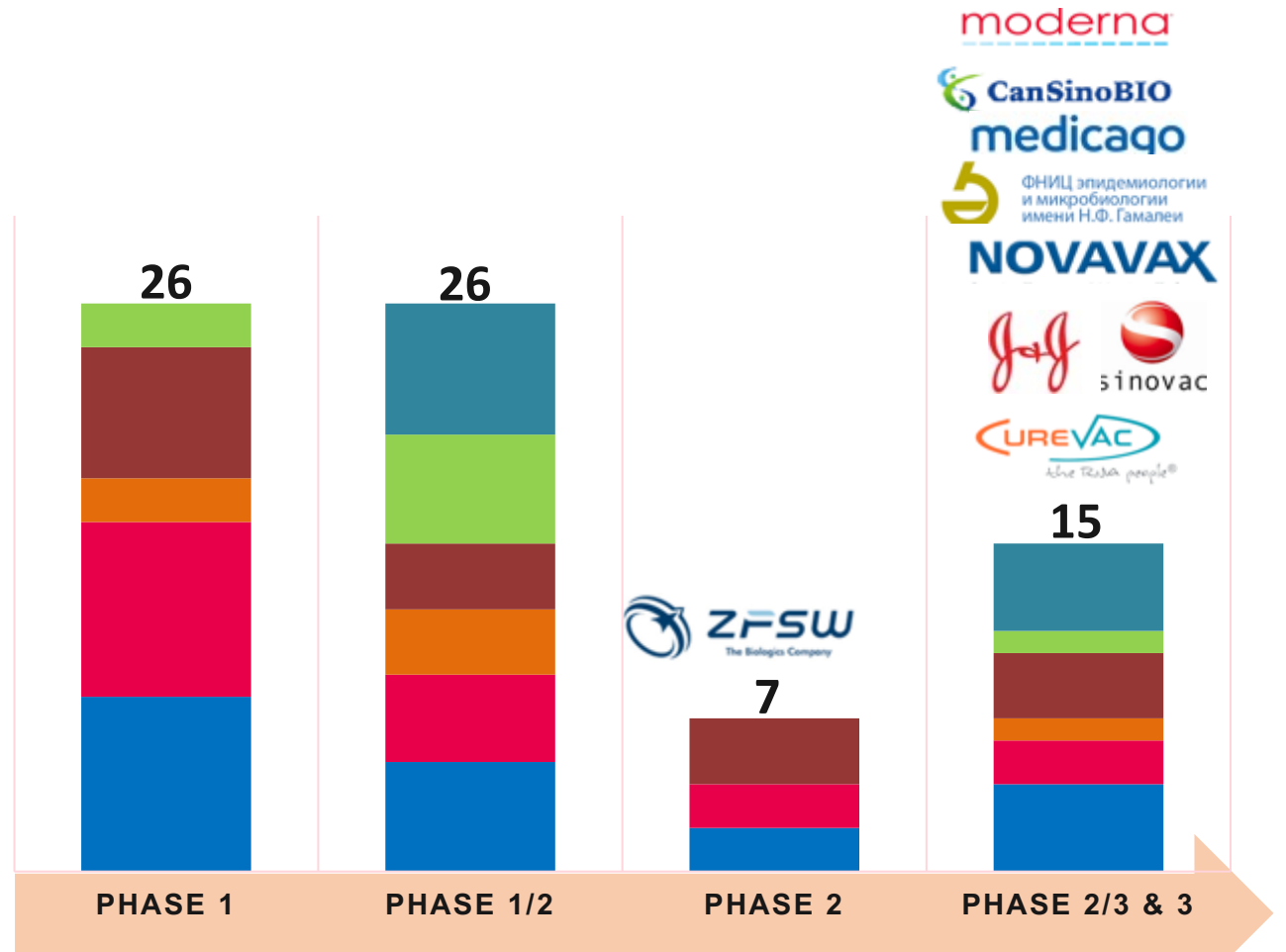


COVID Vaccine Pipeline Diversity

- Viral Vector
- mRNA
- DNA
- Protein subunit
- Inactivated Virus
- Other

280+

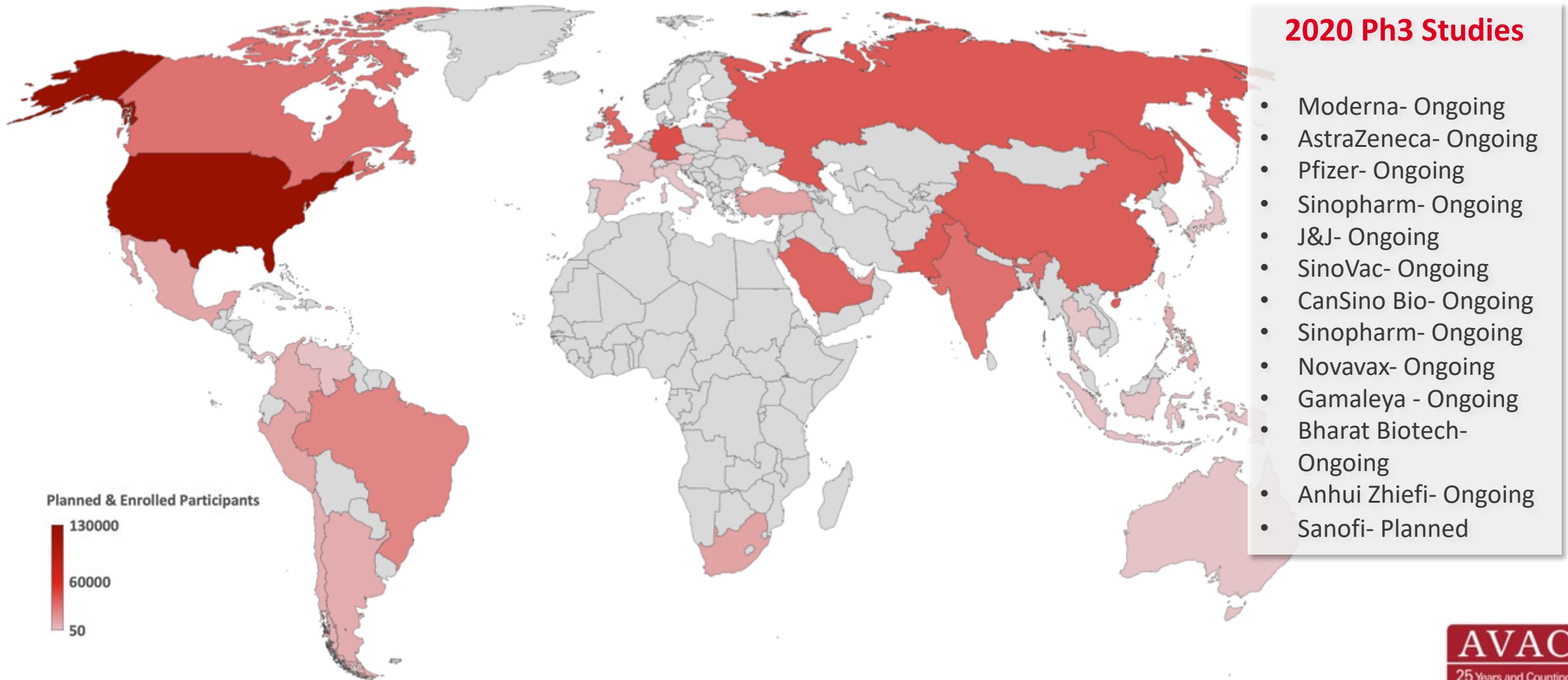
pre-clinical
development



**does not include repurposed vaccines*

Planned Clinical Trials

December 2020



AVAC Resources

- [COVID Vaccine Overview/Cheat Sheet on Platforms and Products](#)
- [Advocates Guide to the risks, benefits, and potential opportunities and complications of expedited COVID vaccine research](#)
- [Regulatory Approval Primer for Vaccine Advocates](#)
- [Advocate's Guide to COVID-19 Vaccine Access](#)
- [New York Times Coronavirus Vaccine Tracker](#)
- [US FDA Guidance Document for Development and Licensure of Vaccines to Prevent COVID-19](#)
- [COVID-19 Pipeline](#)
- [COVID Mythbusters](#)
- [COVID Resources](#)

More resources at <https://www.avac.org/covid>