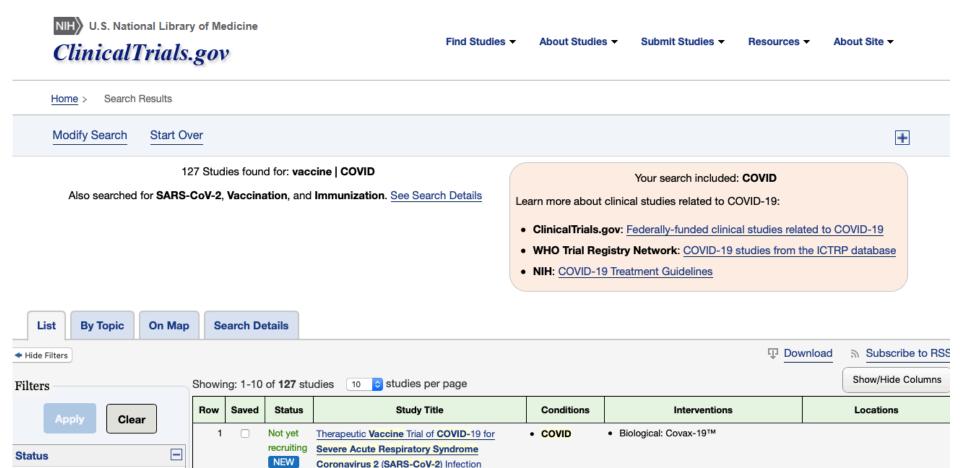
Vaccines for COVID-19. Where Do We Stand?

Timothy F. Murphy MD
SUNY Distinguished Professor
Director, Clinical and Translational Science Institute
Director, Community Health Equity Research Institute
University at Buffalo

Objectives

- Basic principles of clinical trials for vaccines
- Vaccines currently in clinical trials globally and how they work
- Passive and "trained" immunity approaches

Clinicaltrials.gov



Recruiting Safety and Immunity of Covid-19 aAPC Vaccine

Biological: Pathogen-specific aAPC

Treat and Prevent

Covid-19

Infection

· Shenzhen Geno-immune

Shenzhen, Guangdong, China

Medical Institute

Recruitment 1 :

Recruiting

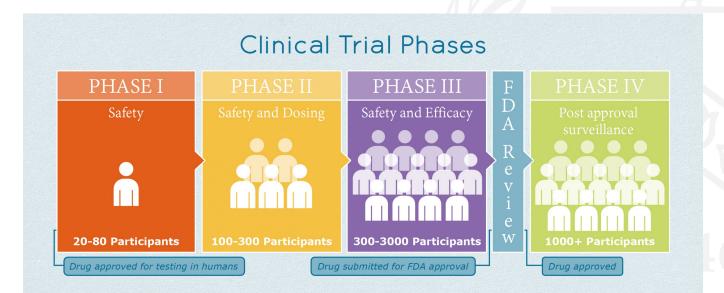
Not yet recruiting

Enrolling by invitation

2

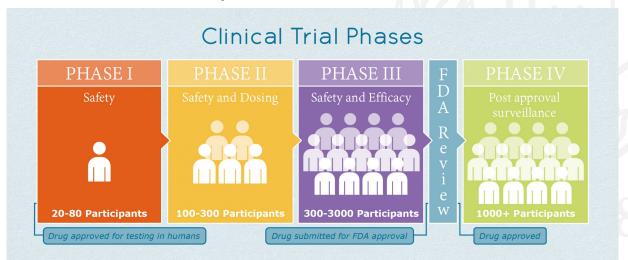
Clinical Trials

- Phase I Clinical Trial
 - Healthy volunteers, primarily safety testing, escalating doses, 20 to 100 participants
- Phase II Clinical Trial
 - Test for side effects and preliminary efficacy; therapeutic doses; 100 - 300 participants with specific disorder

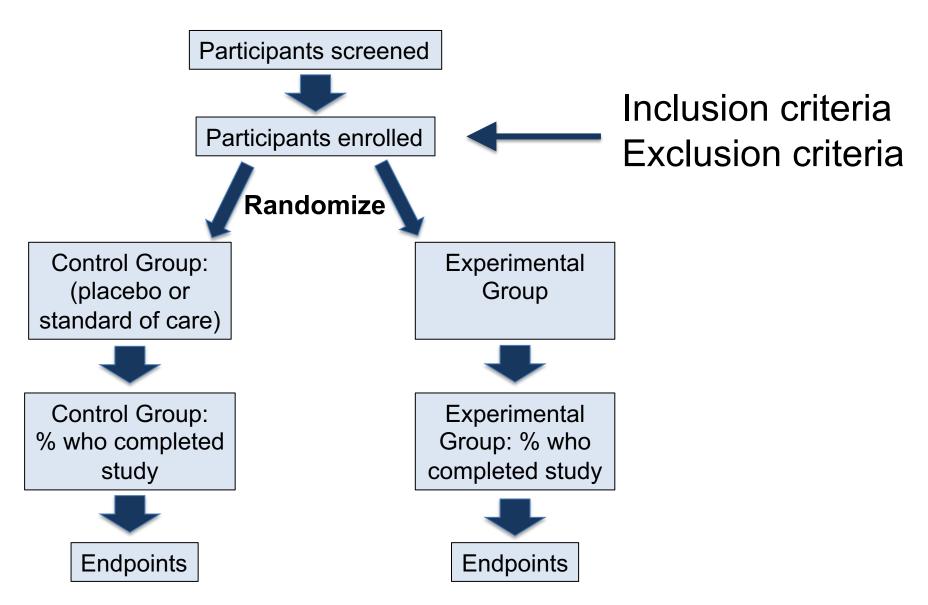


Clinical Trials

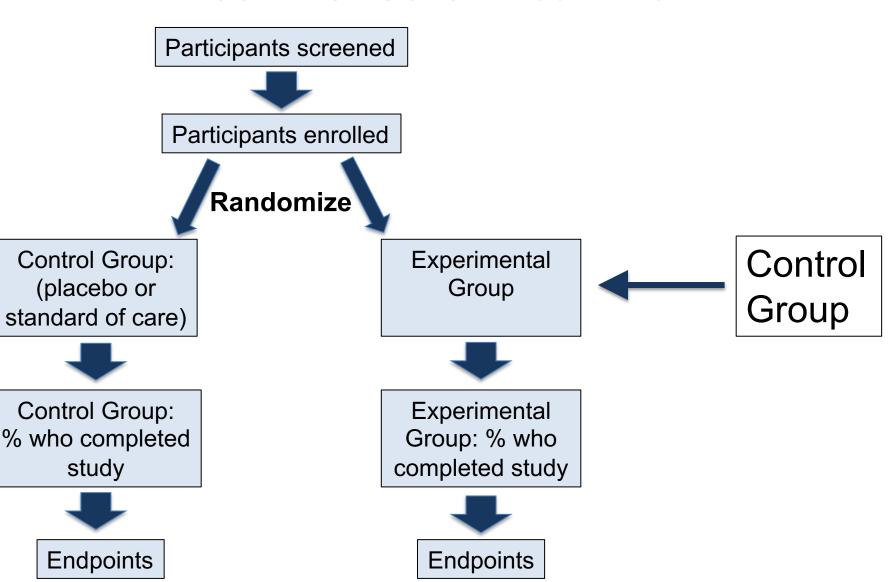
- Phase III Clinical Trial
 - Assess efficacy, effectiveness and safety; 300 to 3,000 participants with specific characteristics
 - Randomized, double-blind, placebo-controlled clinical trial is the gold standard for determining efficacy
- Phase IV Clinical Trial
 - Post marketing surveillance; assess long term effects including effectiveness and safety



Participants screened Statistical Power Participants enrolled Randomize Experimental Control Group: (placebo or Group standard of care) Control Group: Experimental Group: % who % who completed completed study study **Endpoints Endpoints**



Participants screened Participants enrolled Randomization Randomize **Control Group:** Experimental (placebo or Group standard of care) **Control Group:** Experimental Group: % who % who completed completed study study **Endpoints Endpoints**



Participants screened

Participants enrolled

Randomize

Control Group: (placebo or standard of care)



Control Group: % who completed study



Experimental Group



Experimental Group: % who completed study



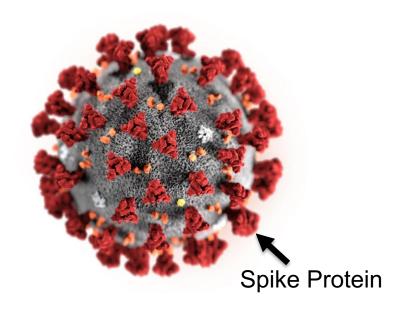
Endpoints -

Endpoints

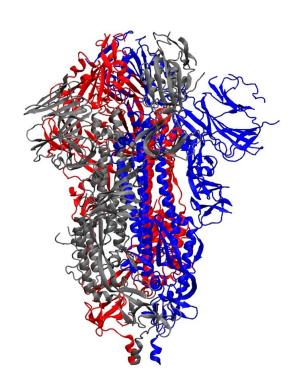




Coronavirus

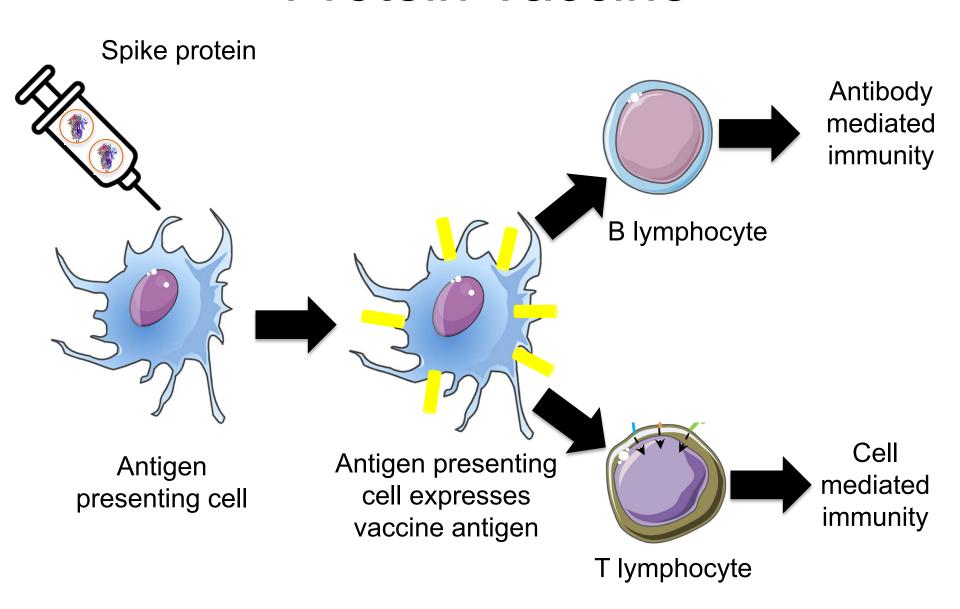


Coronavirus

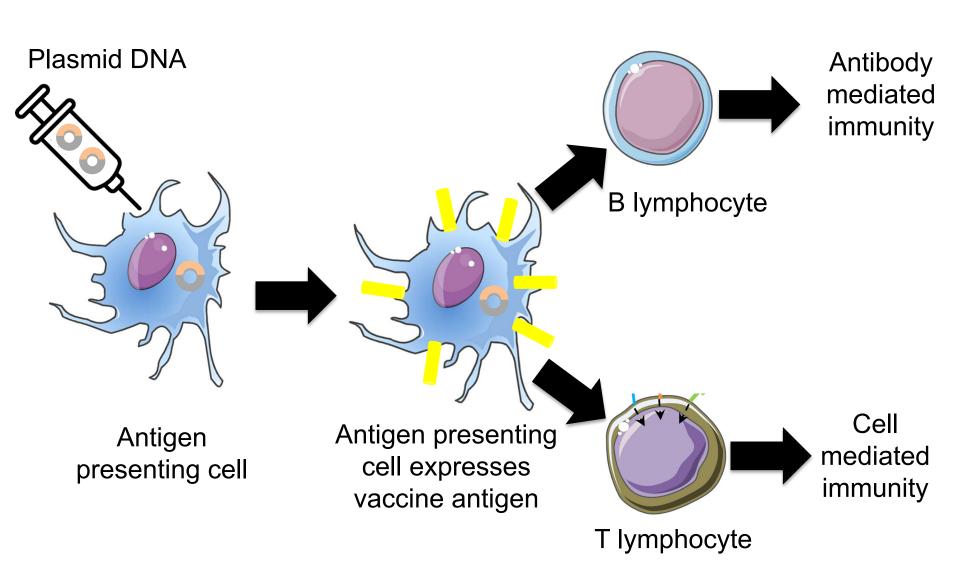


Spike Protein Molecular Model

Protein Vaccine



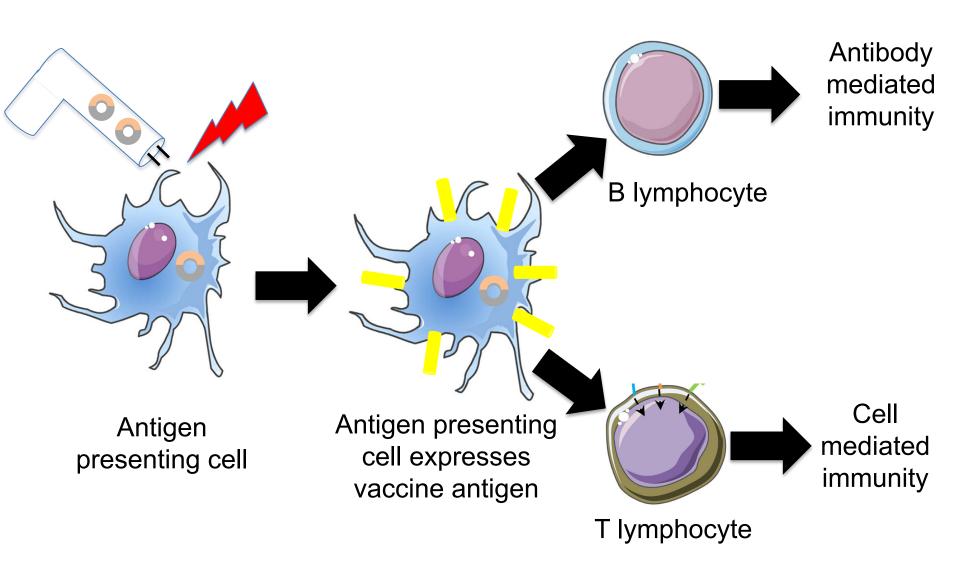
DNA Vaccine



COVID-19 Vaccine Trials

Clinical Trial	Sponsor	Antigen	Carrier / Delivery	Partici- pants
2019 coV Vaccine (mRNA- 1273)	NIAID, Moderna, USA	Spike protein	Novel lipid nanoparticle	45 Healthy volunteers
RNA Vaccine Candidates against COVID- 19	BioNtec, Germany Pfizer, USA	4 Spike protein formulations, 2 domains	Lipid nanoparticle	8640 Healthy volunteers
INO-4800 for COVID-19	Inovio Pharm., PA, USA	Proprietary	DNA vaccine, Cellectra® device, intra- dermal	40 Healthy volunteers

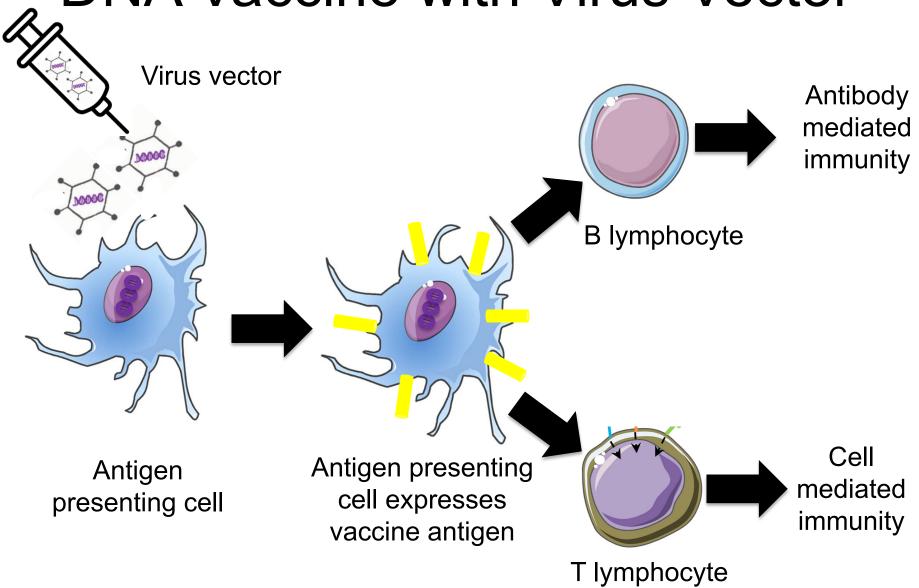
DNA Vaccine with Electroporation



COVID-19 Vaccine Trials

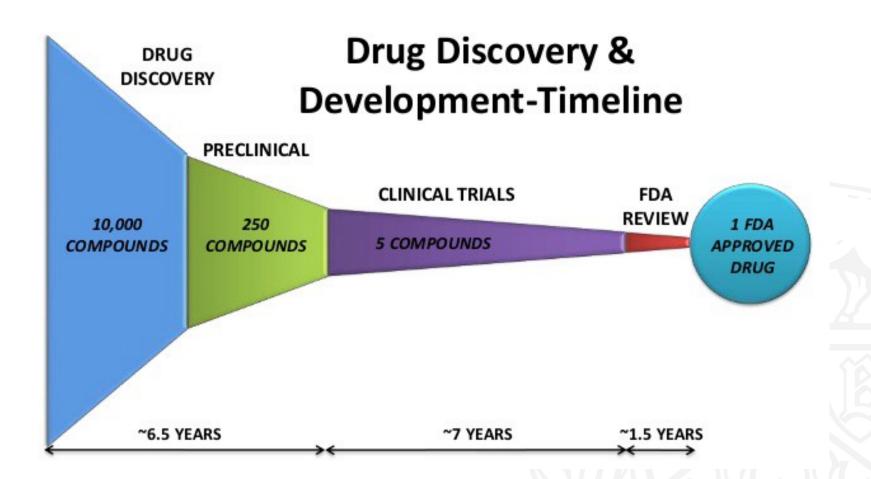
Clinical Trial	Sponsor	Antigen	Carrier / Delivery	Partici-pants
COVID-19 Vaccine ChAdO x1 nCoV-19	Oxford University UK	Spike protein	Adenovirus vector	1112 Healthy volunteers
Recombinant Novel Coronavirus Vaccine	Academy of Military Medical Sciences, China	Spike protein	Adenovirus vector	500 Healthy volunteers
Covid-19 aAPC Vaccine	Shenzhen Geno-Immune Inst, China	DNA of viral proteins, protease	Lentivirus, antigen presenting cells	100 Healthy volunteers
Covid-19 Synthetic Minigene Vaccine	Shenzhen Geno-Immune Inst, China	DNA of viral proteins, protease	Lentivirus, antigen presenting cells, T cells	100 Covid-19 infected patients

DNA Vaccine with Virus Vector



COVID-19 Vaccine Trials

Clinical Trial	Sponsor	Antigen	Carrier / Delivery	Participants
Inactivated Vaccine for SARS CoV-2 Infection	Sinovac Biotech, China	Chemically inactivated virus	Intramuscular injection	744 Healthy volunteers
Inactivated SARSoCoV-2 Vaccine	Chinese Academy of Sciences	Inactivated virus	Intramuscular injection	942 healthy volunteers



\$1 to \$2 billion

Collins. Science Translational Med 3:1, 2011 Munos. Nat Rev Drug Discov 8:959, 2009 Paul et al. Nat Rev Drug Discov 9:203, 2010

- Passive Immunity
 - Convalescent plasma
 - Monoclonal antibodies to spike protein
- "Trained" Immunity
 - BCG
 - Oral poliovirus vaccine
 - Measles vaccine

ACTIV Partnership

Accelerating COVID-19 Therapeutic Interventions and Vaccines



Getting Involved

- Buffalo Research Registry
- www.buffalo.edu/ctsi/brr

- Participate in Research portal
 - www.buffalo.edu/ctsi/pir

Participate in Research

Search and volunteer to participate in these available studies at UB. Your participation in research doesn't just benefit you, it helps advance healthcare for our entire community.

Be an Informed Participa...

Highlighted Searches

Healthy Volunteer

COVID-19 and Infectious Diseases

Mental & Behavioral Health

Dental Health

Lung & Respiratory Health Diet / Obesity / Weight

Multiple Sclerosis

Show More

Search Clinical Trials

Filter on any fields below

Keyword 🕜

i.e. asthma



Enrollment Update

Due to COVID-19, new enrollment in research studies will be greatly limited. If you are interested in a study, there may be a longer waiting period to receive a response to your inquiry. View the guidance for research participants 🖹 for additional information.

Sources of Reliable Information

Clinical Trials

https://clinicaltrials.gov

Erie County Department of Health https://www2.erie.gov/health/

New York State Department of Health https://health.ny.gov

US Center for Disease Control https://www.cdc.gov

Johns Hopkins Coronavirus Resource Center https://coronavirus.jhu.edu/map.html