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Vaccines for the Prevention of COVID-19: An Unprecedented Need – An Unprecedented Response

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COVID-19 Vaccine Development

Operation Warp Speed (OWS)

- OWS is a partnership of the Department of Health and Human Services and the Department of Defense.
  - GOAL: To accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics.

- COVID-19 Prevention Network (CoVPN) is a functional unit of OWS, formed by the National Institute of Health (NIH) to respond to the global pandemic.
  - The Mission: To conduct Phase III efficacy trials for COVID-19 vaccines and monoclonal antibodies.

Warp Speed ≠ Skipped Steps

https://www.coronavirusspreventionnetwork.org/

Clinical Trial Phases for Vaccine Candidates

PHASE 1

Is the vaccine safe?

20-100 healthy volunteers

PHASE 2

What's the immune system response?

Few hundred to 1000 volunteers

PHASE 3

Does the vaccine prevent infections?

Does it reduce severity?

1000s of volunteers

Safety is monitored through all phases

The Vaccine Production Process

Normal vaccine production timeline: 8–15 years
Target for COVID-19 vaccine: 12–18 months*

1. Research

Normal: 2–4 years
Accelerated: 6 months

2. Preclinical preparation

Normal: 2 years
Accelerated: 6 months

3. Clinical trials

Normal: Up to 5 years
Accelerated: 1.5 years

4. Approval

Normal: 1 year
Accelerated: 6 months

5. Manufacturing

Normal: 2 years
Accelerated: 3–6 months

6. Distribution

Normal: 3–6 months
Accelerated: 1 month

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Primary Objectives:

- Is the study vaccine safe to give to people?
- Can the study vaccine reduce the severity and frequency of COVID-19 illness?

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Janssen & AstraZeneca Vaccines

Janssen Study Overview

- **Phase 3** randomized, double-blinded, placebo-controlled clinical trial (60,000 people nationally)
- **How it works:**
  - Based on a weakened version of a common cold (adenovirus) virus
  - Changed so that it can't replicate inside your body
  - Presents bits of genetic material copied from the spike protein to teach the body to recognize the virus and fight against it
- **Injection schedule:**
  - 1 single injection
  - 1:1 randomization ratio of investigational vaccine to placebo (salt water)

AstraZeneca Study Overview

- **Phase 3** randomized, double-blinded, placebo-control clinical trial (30,000 people nationally)
- **How it works:**
  - Based on a weakened version of a common cold (adenovirus) virus
  - Changed so that it can't replicate inside your body
  - Presents part of the spike protein to teach the body to fight against the virus
- **Injection schedule:**
  - 2 injections, 4 weeks apart
  - 2:1 randomization ratio of investigational vaccine to placebo (salt water)

Eligibility

Inclusion:

- ≥18 years of age
- Healthy or medically-stable underlying health conditions
- People who are more likely to be exposed to COVID-19:
  - People with greater chances of exposure at their job, who live or work in elder-care facilities, who work in jails or prisons, and from racial and ethnic groups that have been impacted in greater numbers by the epidemic, such as African Americans, Asian/Pacific Americans, Latinos, and American Indians

Exclusion:

- History of laboratory confirmed SARS-CoV-2 infection (only for AstraZeneca)
- Weakened immune system (does not apply to well-controlled HIV)
- Pregnancy/breastfeeding

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Outreach & Recruitment Strategy

San Diego County COVID-19 (as of 12/7/20)

Summary of COVID-19 Cases by City of Residence, San Diego County			
San Diego County	Count	Percentage* of Total	Rate per 100,000 population**
Incorporated City	*79,142*	*86.5%*	*2,790.2*
Carlsbad	1,472	1.6%	1,277.3
Chula Vista	11,503	12.6%	4,238.2
Coronado	355	0.4%	1,467.0
Del Mar	60	0.1%	***
El Cajon	4,604	5.0%	4,361.5
Encinitas	917	1.0%	1,446.6
Escondido	4,519	4.9%	2,958.6
Imperial Beach	1,107	1.2%	4,033.1
La Mesa	1,399	1.5%	2,300.2
Lemon Grove	945	1.0%	3,473.2
National City	2,755	3.0%	4,421.7
Oceanside	3,885	4.2%	2,182.3
Poway	718	0.8%	1,426.9
San Diego	38,457	42.0%	2,707.2
San Marcos	2,211	2.4%	2,247.7
Santee	1,155	1.3%	1,977.5
Solana Beach	159	0.2%	1,141.2
Vista	2,921	3.2%	2,864.1

COVID-19 Vaccine Clinic Locations

3 Mobile Clinic Locations:

- Chula Vista
- Imperial Beach
- La Mesa

Semi-Permanent Site:

- National City

San Diego County COVID-19 (as of 12/7/20)

Summary of COVID-19 Cases by Race/Ethnicity

COVID-19 Case Summary	San Diego County Residents		
Total Positives	**94,169**		
Race and Ethnicity*	**Count**	**% of Total with Known Race/Ethnicity (N= 82,326)**	**Rate per 100,000****
Hispanic or Latino	47,456	57.6%	4,340.3
White	21,091	25.6%	1,396.4
Black or African American	3,112	3.8%	1,847.4
Asian	4,458	5.4%	1,042.5
Native Hawaiian/Pacific Islander	690	0.8%	4,837.4
American Indian/Alaska Native	266	0.3%	1,221.8
Multiple Race	1,165	1.4%	1,078.3
Other Race	4,088	5.0%	
Race/Ethnicity Unknown	11,843		

*Persons of Hispanic/Latino ethnicity may belong to any race group. All categories except Hispanic/Latino include persons for whom race is known but ethnicity is non-Hispanic or unknown.

**Rates are calculated using 2019 population estimates from the San Diego Association of Governments.

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COVID-19 Outcomes by Race/Ethnicity

Rate ratios compared to White, Non-Hispanic Persons	American Indian or Alaska Native, Non-Hispanic persons	Asian, Non-Hispanic persons	Black or African American, Non-Hispanic persons	Hispanic or Latino persons
Cases[1]	2.8x higher	1.1x higher	2.6x higher	2.8x higher
Hospitalization[2]	5.3x higher	1.3x higher	4.7x higher	4.6x higher
Death[3]	1.4x higher	No Increase	2.1x higher	1.1x higher

https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html

Optimizing access to under-represented populations

- **Language barriers**:
  - All materials available in Spanish
- **Geographic barriers**:
  - Mobile sites in the South Bay and La Mesa
- **Longstanding mistrust in research and medicine**:
  - Community education
  - Informed consent

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https://www.covidvaccinesd.com/

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Home | What To Expect | About Us | Learn More | FAQ | Join The Study

WE ARE IN THIS TOGETHER

We have all been impacted by COVID-19, but there is hope.
By joining together to protect our families and communities, we can overcome this challenge.

UC San Diego invites you to be part of the solution by participating in a vaccine clinical trial in San Diego.

We are in this together, and we can get out of this together.

We are proud to partner with the following organizations:

MAAC

FAMILY HEALTH CENTERS OF SAN DIEGO

SAN YSIDRO HEALTH

CALIFORNIA NATIONAL CITY 1887 INCORPORATED

We also want to thank our Community Advisory Committee Members:

Mona AuYoung, Dr. Dan Calac, Veronica Gerace, Vanessa Gonzalez, Daniel Hernandez, Monica Hernandez, Min Kim, Stacey Kurz, Tana Lepule, Sarah Lyman, Blanca Melendrez, Keisha Robinson, Elsa Roth, Sarina Vega

UC San Diego COVID-19 Vaccine Trial Enrollment (as of 12/8/20)

Race / Ethnicity	% of Enrollments	% of SD County*
Hispanic or Latino	21.2%	32.6%
White	56.8%	45.1%
Black or African American	3.4%	5.0%
Asian, Native Hawaiian, & Pacific Islander	9.5%	13.2%
American Indian & Alaska Native	1.3%	0.7%
Multi-Racial	5.4%	3.2%
Other	2.0%	0.2%

*2019 SANDAG population estimates

Research enrollment should be representative of the local community

Equitable Vaccine Distribution

- Underserved communities have expressed mistrust of vaccine effort
- If limited vaccine available, CoVPN leadership and other key leaders will “establish recommendations for priority populations that should receive the vaccines first”
- Organization is happening now to guarantee that communities we are asking to participate are not later left behind

Phase 1

Phase 1a "Jumpstart Phase":

- High-risk workers in health care facilities
- First responders

Phase 1b:

- People of all ages with comorbid and underlying conditions that put them at significantly higher risk
- Older adults living in congregate or overcrowded settings

Phase 2

- Critical risk workers—workers who are both in industries essential to the functioning of society and at substantially high risk of exposure
- Teachers and school staff
- People of all ages with comorbid and underlying conditions that put them at moderately higher risk
- All older adults not included in Phase 1
- People in homeless shelters or group homes for individuals with physical or mental disabilities or in recovery
- People in prisons, jails, detention centers, and similar facilities, and staff who work in such settings

Phase 3

- Young adults
- Children
- Workers in industries essential to the functioning of society and at increased risk of exposure not included in Phase 1 or 2

Phase 4

- Everyone residing in the United States who did not receive the vaccine in previous phases

Equity is a crosscutting consideration: In each population group, vaccine access should be prioritized for geographic areas identified through CDC's Social Vulnerability Index.

DRAFT

https://www.nap.edu/catalog/25914/discussion-draft-of-the-preliminary-framework-for-equitable-allocation-of-covid-19-vaccine

Final thoughts…

- How do we engage your community in clinical trial participation?
- Sign up for the study at www.covidvaccinesd.com (or www.vacunacovidsd.com in Spanish).
- Promote community education by inviting us to speak to your team/organization and community members.

Questions?

Email Marvin Hanashiro @ mhanashiro@health.ucsd.edu

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