Advances in HIV Vaccine Clinical Research (Lessons Learned) and our Vision for the Future

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HIV VACCINE TRIALS NETWORK

Who is the HVTN?

The HVTN is an international collaboration of scientists, clinical trial sites, and community representatives working with governments and industry in the global search for an HIV vaccine with a goal of speeding the development and testing of HIV vaccine candidates.

What is the HVTN?

- The HVTN is the **world's largest publicly funded clinical trials program** dedicated to finding an effective HIV vaccine.

- The HVTN is **funded largely by the Division of AIDS (DAIDS) in the National Institute of Allergies and Infectious Disease (NIAID)** at the US National Institutes of Health (NIH), which is part of the US Dept. of Health and Human Services (DHHS).

- Specific projects are funded by:

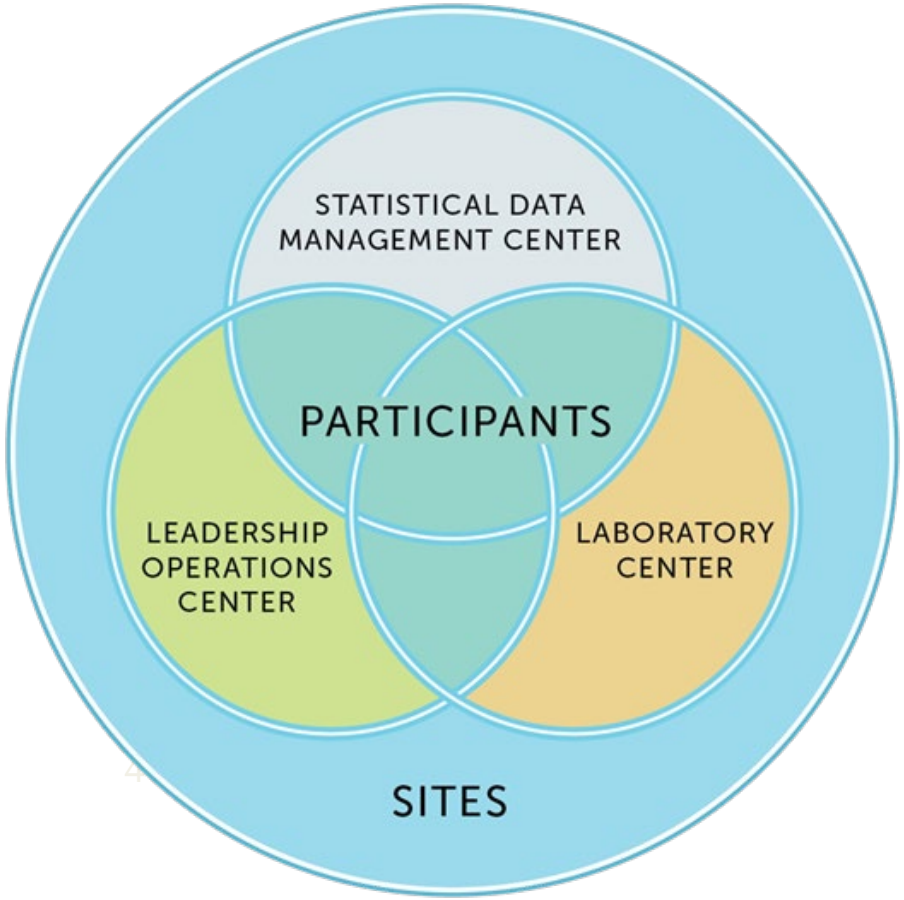
  Bill and Melinda Gates Foundation

  South African Medical Research Council

  Janssen Vaccines and Prevention

HIV VACCINE
TRIALS NETWORK

How is the HVTN Organized?



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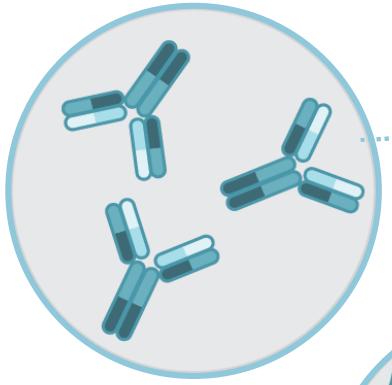
HVTN: 2000 to Present

HVTN Studies

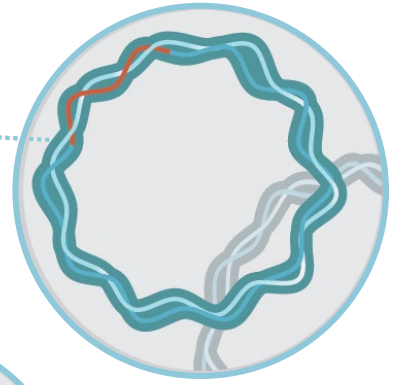
Viral Vector

Protein

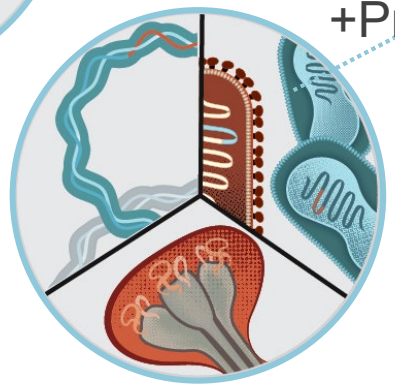


Monoclonal Ab

DNA

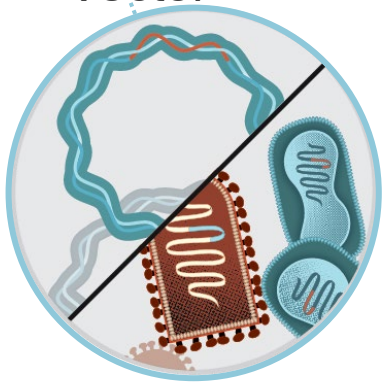


DNA+Viral Vector +Protein

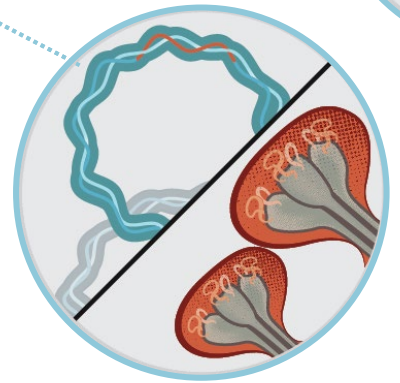


Viral Vector+Protein

DNA+Viral Vector



DNA+Protein



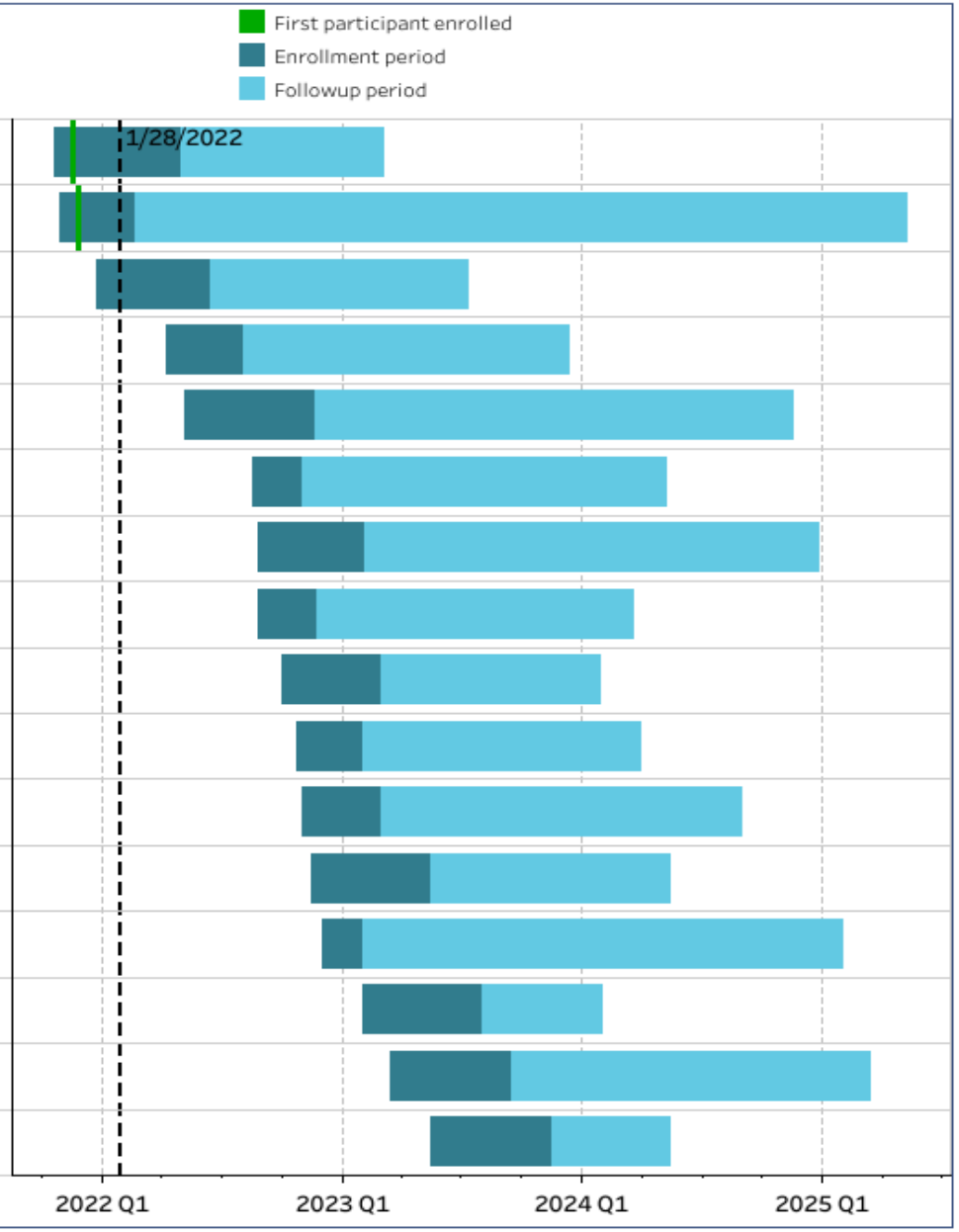
Protocol pipeline: Phase 1 studies

Filter protocols
Multiple values

Date data refreshed
January 28, 2022 1:02 PM

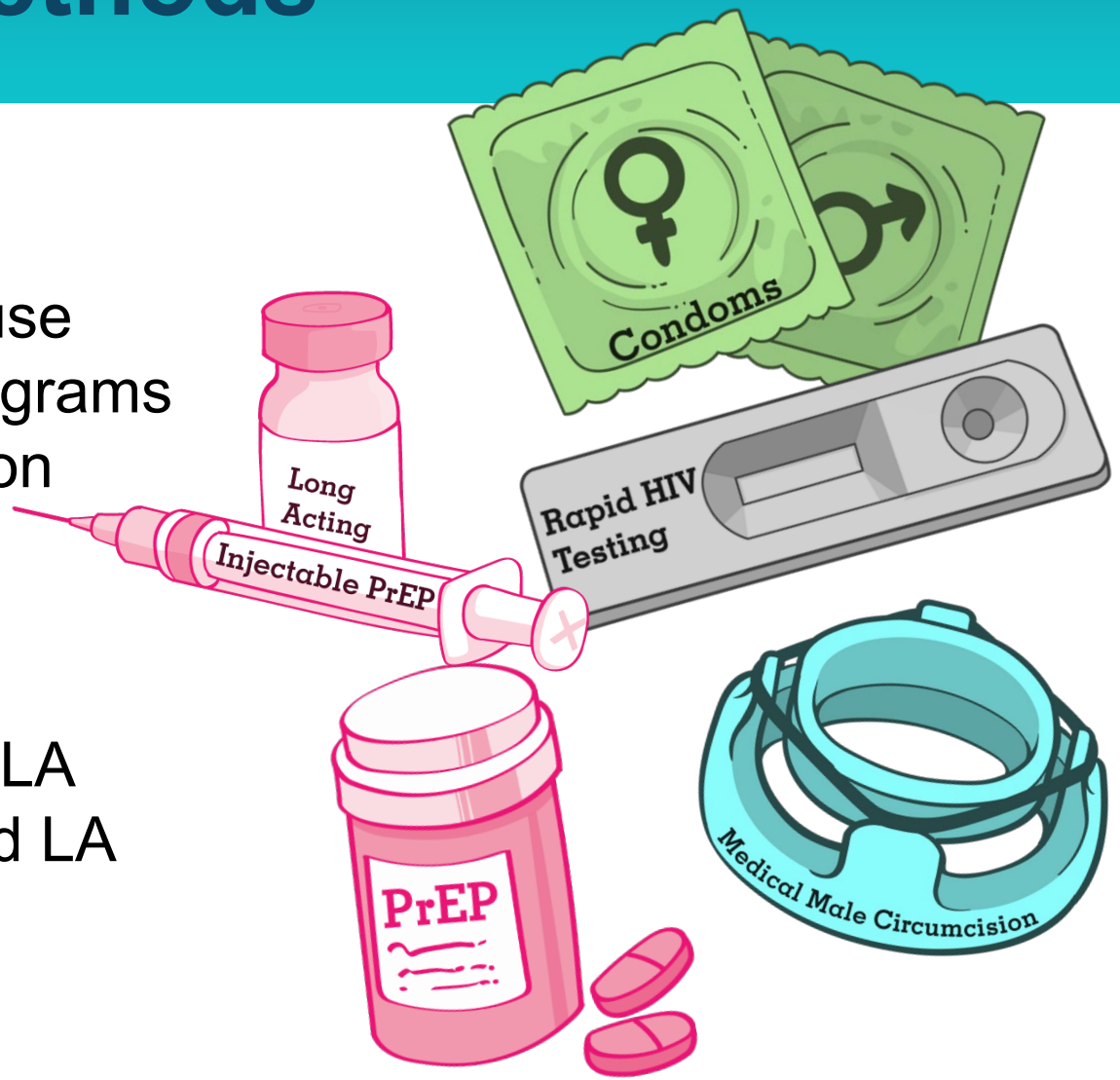
Timeline projections for future studies are subject to change.

Protocol Name	Concept Name	Study N	Protocol Open
HVTN140/HPTN101	PGDM1400LS + combo mAb	95	10/20/2021
HVTN139	Chimp Ad 6/7 Clade C Env + gp1..	36	10/28/2021
HVTN302	Scripps HIV Trimer mRNA	108	12/23/2021
HVTN301	Stamatatos (426c.Mod.Core-C..	52	4/7/2022
HVTN303	VRC019 Fusion Peptide Vaccine	70	5/6/2022
HVTN304	Wistar synDNA (AB05 + Trimer ..	10	8/18/2022
16055 NFL trimer, ..	16055 NFL trimer, Clade C (Scri..	36	8/24/2022
HVTN305	Wistar sD-NP-GT8	54	8/24/2022
HVTN604/IMPAAC..	VPM1002 and BCG re-vaccinati..	480	9/30/2022
N332 GT5 stabilize..	N332 GT5 stabilized native-like..	128	10/22/2022
HVTN306	Duke; V3G CH848 mRNA-NP1 a..	34	11/1/2022
bnAb ATI (3BNC11..	bnAb ATI (3BNC117-LS, 10-107..	30	11/15/2022
CH505TF trimer + ..	CH505TF trimer + empty LNPs (..	36	12/1/2022
HCMV-HIV Mfuse1 ..	HCMV-HIV Mfuse1 (VirBio)	144	2/1/2023
HVTN307	Duke; V3G CH848 prNP1+ mRN..	18	3/15/2023
EbnAb Combo	EbnAb Combo	107	5/15/2023



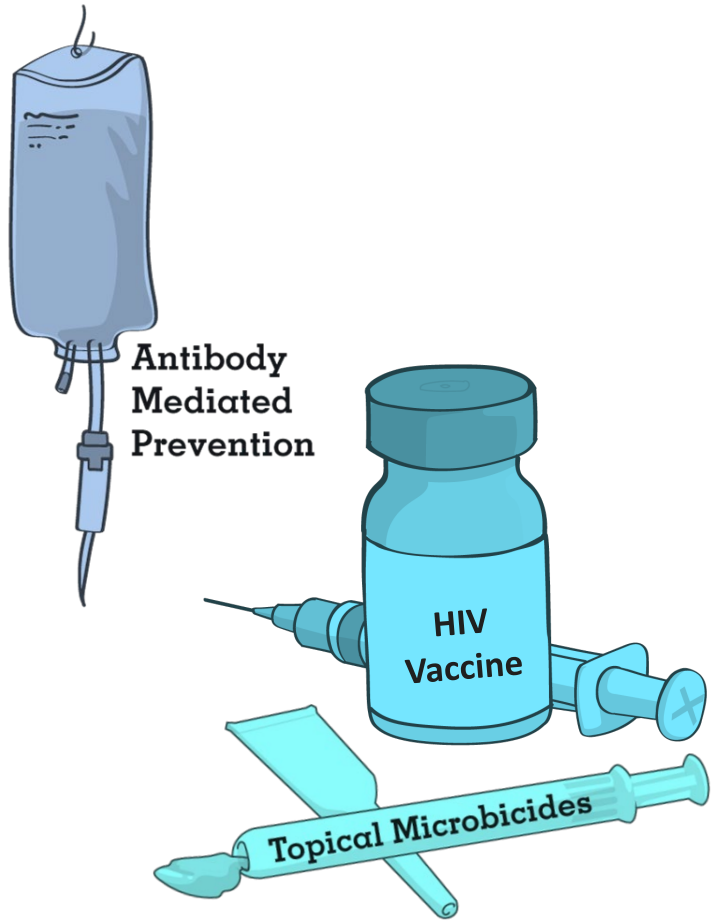
Approaches to HIV Prevention: Available Methods

- Education and behavior modification
- Condoms and other barrier methods
- Treatment/prevention of drug/alcohol abuse
- Clean syringes, i.e. needle exchange programs
- Interruption of mother-to-child transmission
- Medical Male Circumcision (MMC)
- HIV and STI Testing (Know your status!)
- Post-exposure prophylaxis (PEP)
- Treatment as prevention (TasP) oral and LA
- Pre-exposure prophylaxis (PrEP) oral and LA



Approaches to HIV Prevention: Still Being Researched

- Treating other **s**exually **t**ransmitted **i**nfections (STIs)
- Use of Vaginal Rings
- Topical microbicides (rectal or vaginal)
- Antibody Mediated Prevention
- HIV Vaccines



Historical Use of Vaccines and Why An HIV Vaccine Is Needed

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History of Preventive Vaccines

- Used for decades around the world, most commonly in children
- Safe when manufactured and used properly
- Cost-effective compared to treatment
- Eliminated smallpox worldwide
- 2008: 1st vaccine for girls and young women against a cancer-causing virus, human papilloma virus (HPV), and 2009-10 approval for boys and young men

Vaccine Research in Perspective

VACCINE	DISCOVERY OF VIRUS	VACCINE DEVELOPED FOR HUMAN USE	YEARS TO VACCINE
H. Influenzae-B	1892	1985	93
Herpes (HSV-1)	1919	Not available	>90
Pertussis	1906	1926	20
Polio	1909	1954	47
Yellow Fever	1900	1935	35
Influenza	1933	1945	12
Measles	1911	1957	46
Hepatitis A	1973	1995	22
Hepatitis B	1967	1984	17
HPV	1974	2007	33
HIV	1983	Not available	>30

The Impact of Vaccines in the United States

DISEASE	BASELINE 20TH CENTURY PRE-VACCINE ANNUAL CASES	2008 CASES*	PERCENT DECREASE
Measles	503,282	140	99.9%
Diphtheria	175,885	0	100.0%
Mumps	152,209	454	99.7%
Pertussis	147,271	10,735	92.7%
Smallpox	48,164	0	100.0%
Rubella	47,745	16	99.9%
Haemophilus influenzae type b, invasive <5 yrs.)	20,000	30	99.9%
Polio, paralytic	16,316	0	100%
Tetanus	1,314	19	98.6%

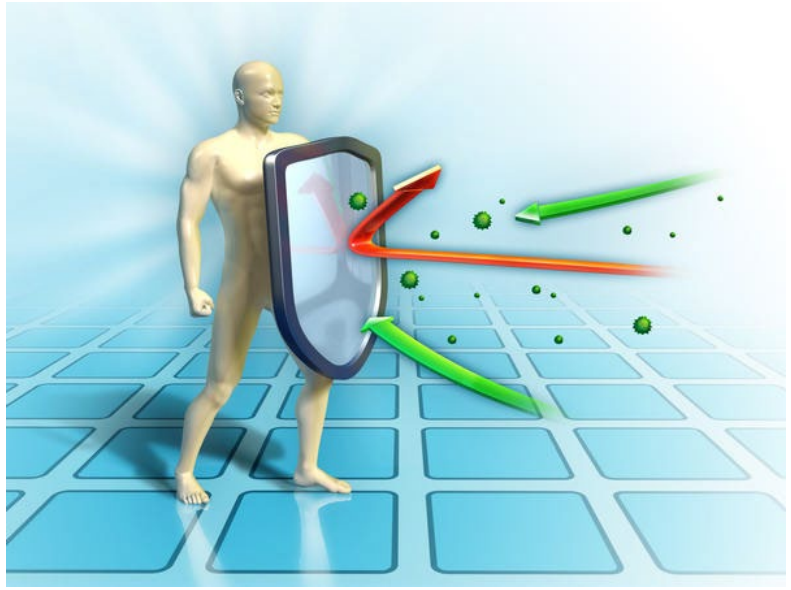
***Provisional**

Source: *MMWR* 4/2/99, 12/25/09, 3/12/2010

HIV VACCINE TRIALS NETWORK

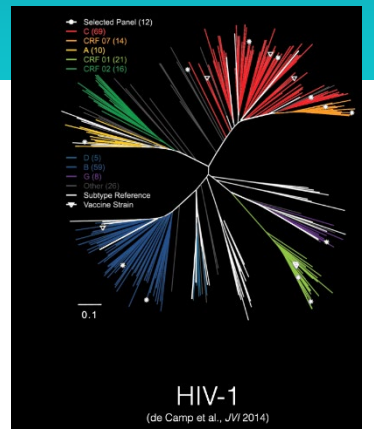
An HIV Vaccine is More Challenging

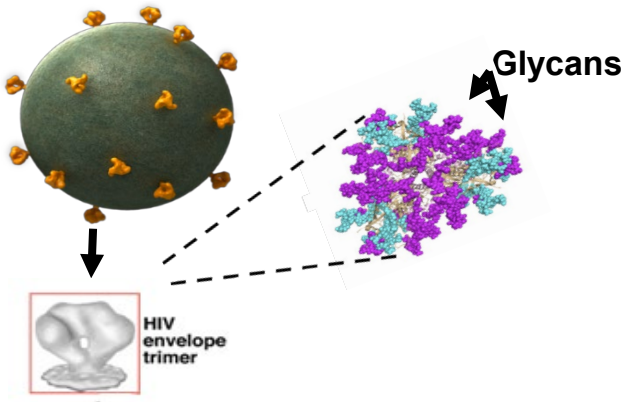
- The only people who have a natural protective immunity to HIV are those with a genetic mutation to their CCR5 receptor (mostly of Western European ancestry).
- We have to do better than Mother Nature – need to induce "unnatural" protective immunity.
- This immunity needs to be a rapid response, and in all the right locations.
- People are bombarded with myths and misinformation.
- People who want to help don't know how.
- Volunteers may be stigmatized by a vocal anti-vax movement; politics interfering with science



HIV Challenges

- HIV sequence diversity
- HIV evades immune surveillance
  - bnAb induction will likely require complex immunization regimens
- Effective prevention or control of HIV may require sustained protective responses to multiple epitopes (bnAbs and/or T cells)
- Latent HIV reservoirs are established early during acute infection





We need a vaccine.

…to respond to global *and* local HIV epidemics.

- **Globally**
  - In 2016, 36.7 million people globally are living with HIV/AIDS.
  - About 1.8 million people became newly infected in 2016.

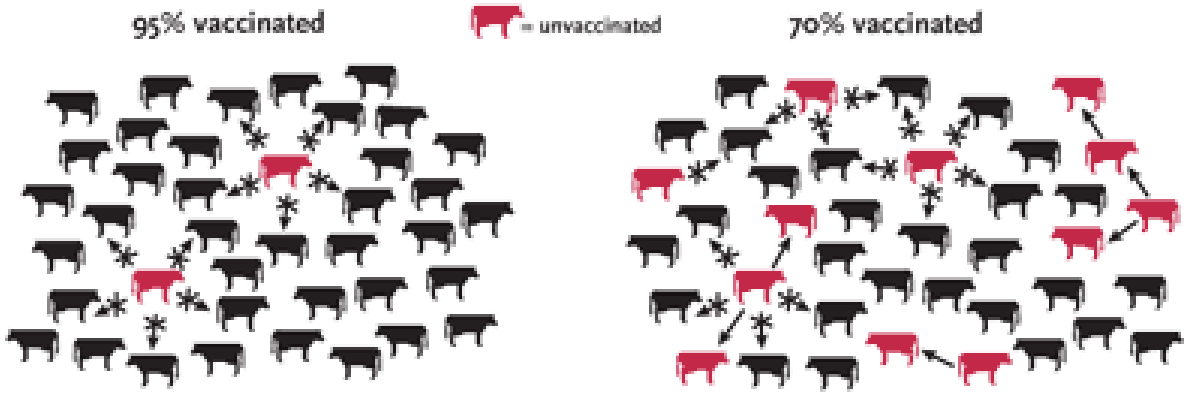
- **United States** (as of 2019)
  - There are over 34,800 new HIV infections every year.
  - New infections are highest among communities of color.

<u>The sociocultural context is also important!</u>

What Might a Preventive HIV Vaccine Do?

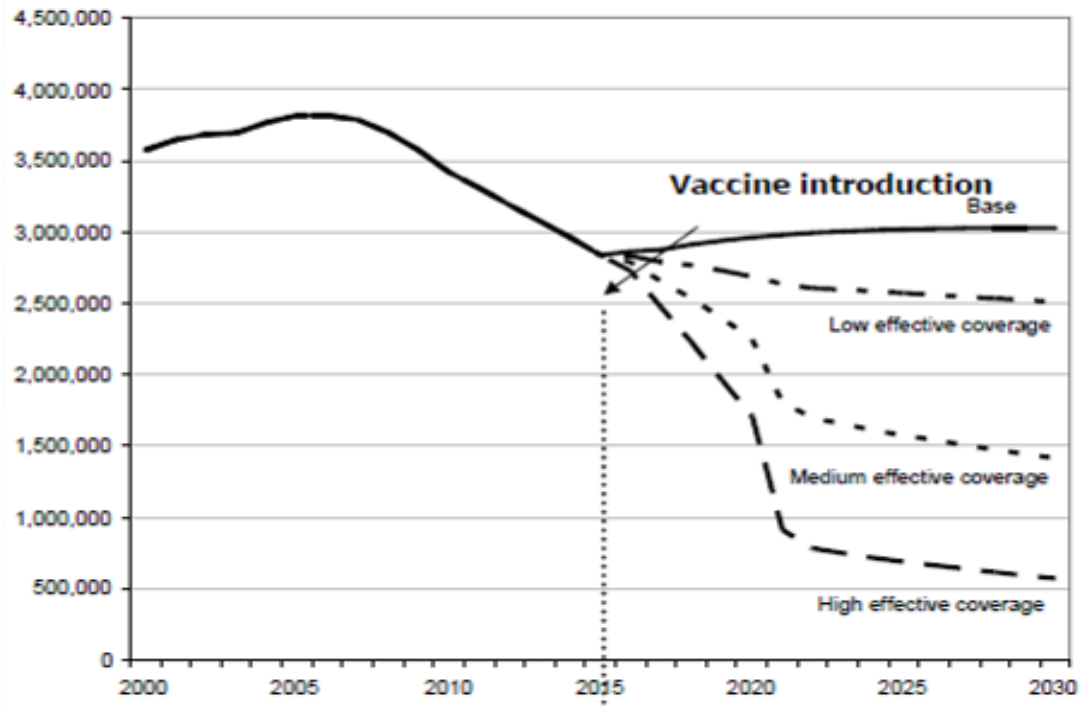
- Potential Benefits for the person who gets the vaccine:
  - ☑ Prevent infection
  - ☑ Prevent disease
  - ☑ Delay disease progression

- Potential Benefits for the entire community:
  - ☑ Prevent further transmission
  - ☑ Create “community immunity”



Potential Impact of a Vaccine

New Adult Infections in Low- and Middle- Income Countries by Year and Vaccine Scenario



Total new infections averted by an AIDS vaccine between 2015-2030

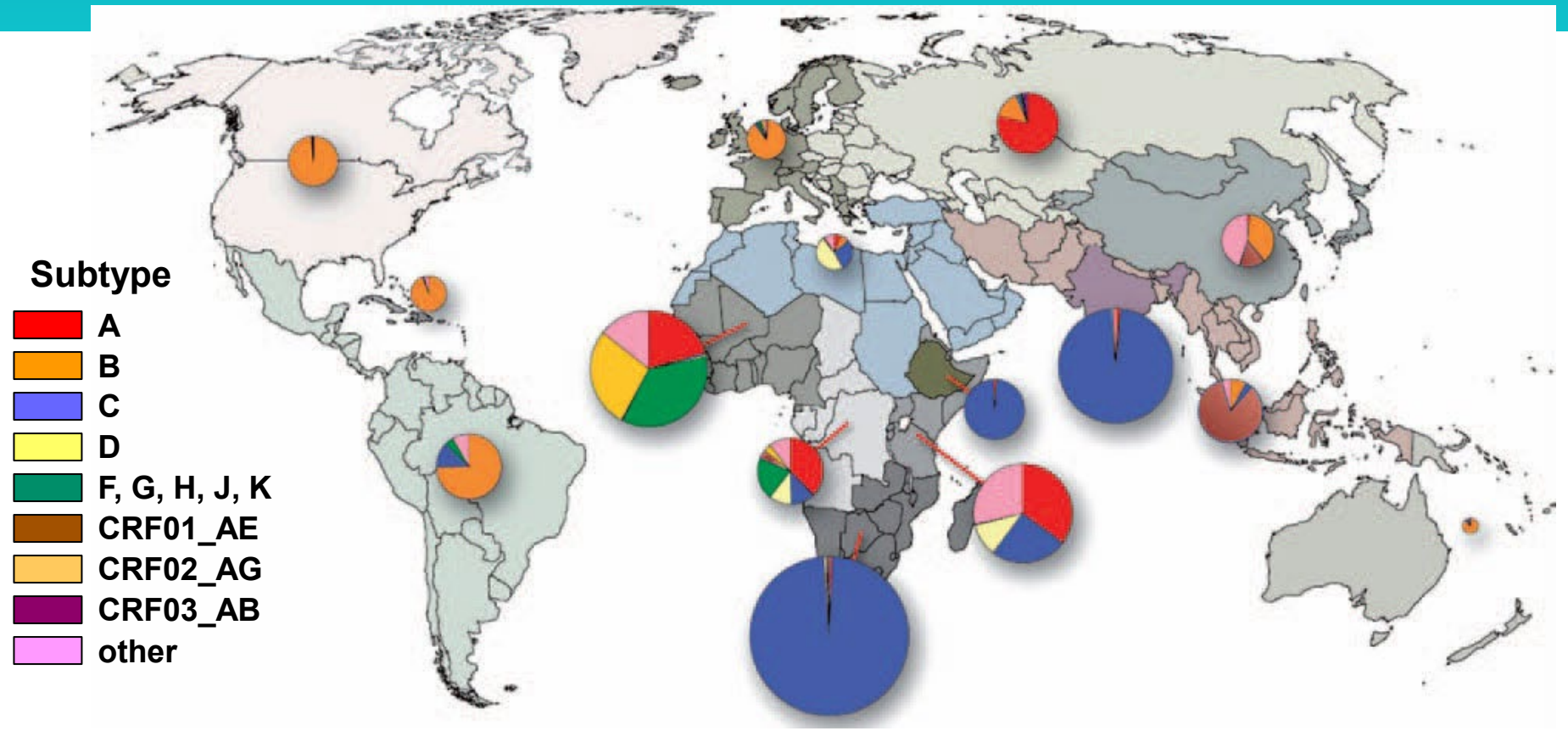
30% efficacy, 20% coverage	5.5 million
50% efficacy, 30% coverage	17 million
70% efficacy, 40% coverage	28 million

Even a vaccine with low efficacy and limited coverage can impact the epidemic and play a role in preventing future infections

Stover J, et al. The impact of an AIDS Vaccine in Developing Countries: A New Model and Initial Results. Health Affairs 26(4):1147-1158 (2007)

HIV-1 Diversity Worldwide

HIV-1 group M: 9 subtypes & several circulating recombinant forms



HIV genomes differ by 10-30%

Human genomes differ by about 0.1%

Hemelaar et al. 2004. WHO/UNAIDS.

Brief Intro to Immunology

HIV VACCINE
TRIALS NETWORK


ADAPTIVE
CELLULAR
CD8
CD4 "Helpers"
HUMORAL
B-CELLS
Antibodies
BOTH
Dendritic
INNATE
Epithelial Cells
Macrophages
Complement System
NK cells

Innate Response

- First line of defense
- Prevents infection? No!
- NK cells activated when cells are infected
- Activation of innate response is required before the adaptive response can happen
- No immunological memory
- We don’t think vaccination will help with immunological memory
- NK cells work by causing infected cells to burst, like a dart bursting a water balloon

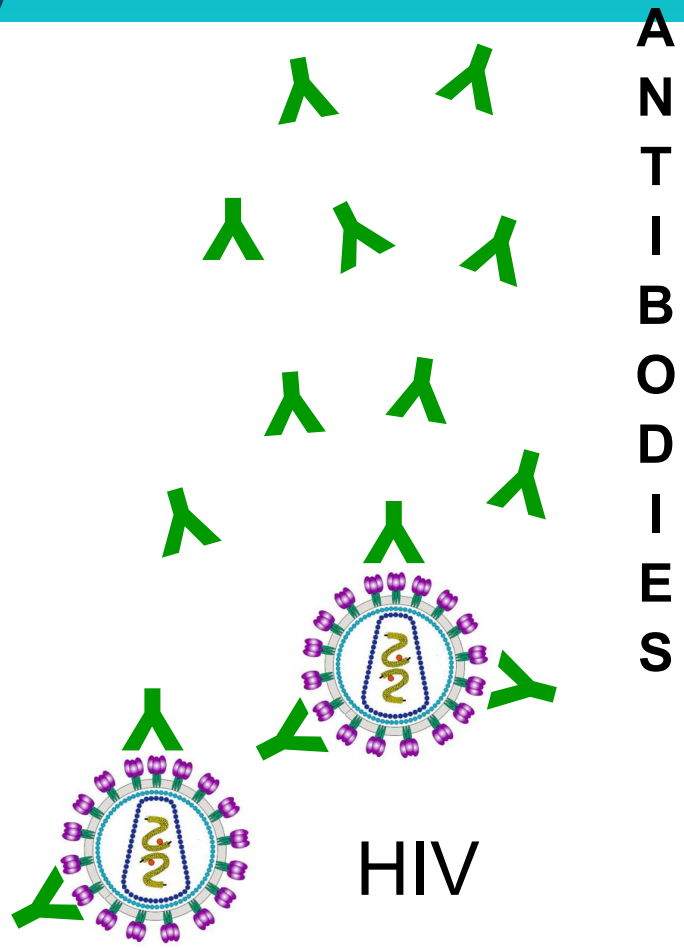

CD8
CD4 "Helpers"
CELLU AR
HUMORAL
B-CEL S
Antibodies
Dendritic
ADAPTIV
BOTH
INNATE
Epithelial Cells
Macrophages
Complement System
Cytokines
NK cells

Adaptive = Acquired

- **Antigen-specific defense mechanism**
- **Takes several days to become protective**
- **Develops throughout life**

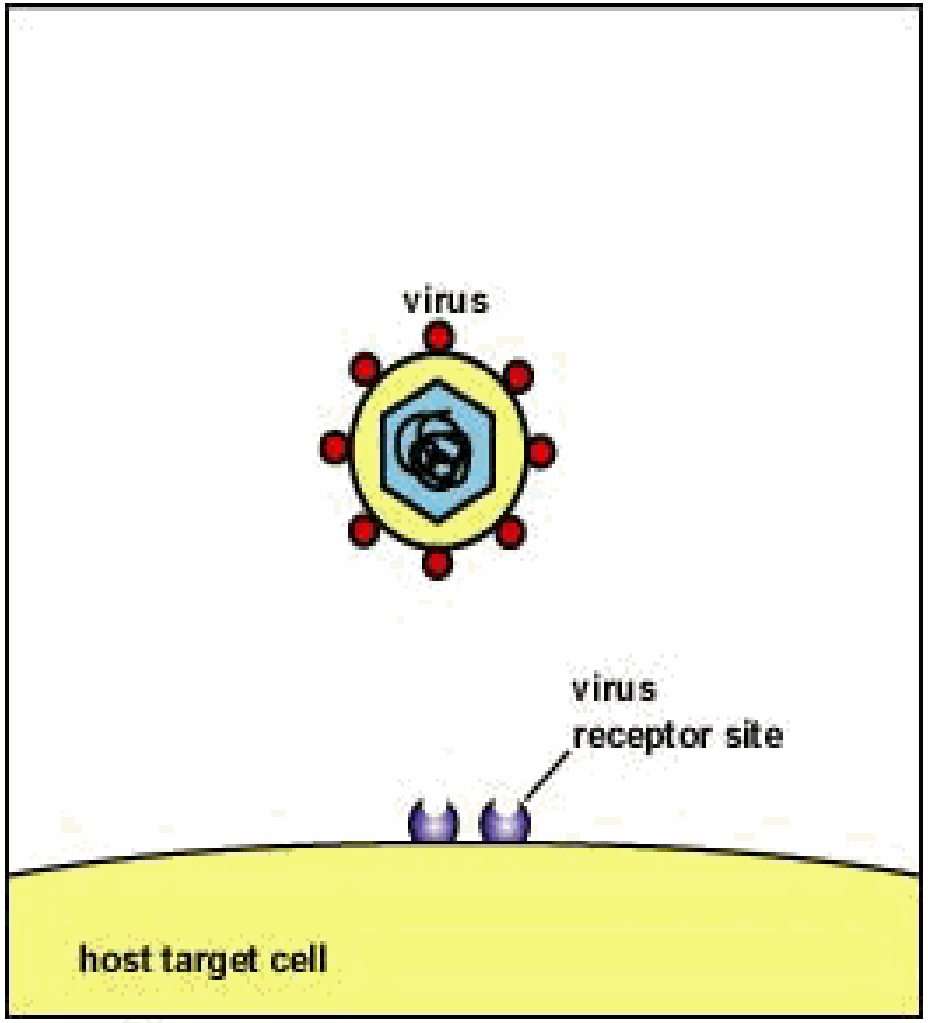
Adaptive – Part 1
(also known as humoral or antibodies)

- Antibodies are made by B cells in the first 2 days after infection, but usually takes 2 weeks for full effect
- Antibodies have three simultaneous functions:
  - neutralize or stop the virus
  - eliminate the virus through opsonization
  - sensitize the immune system to engage other functions
- Antibodies can prevent infection
- Antibodies have immunological memory

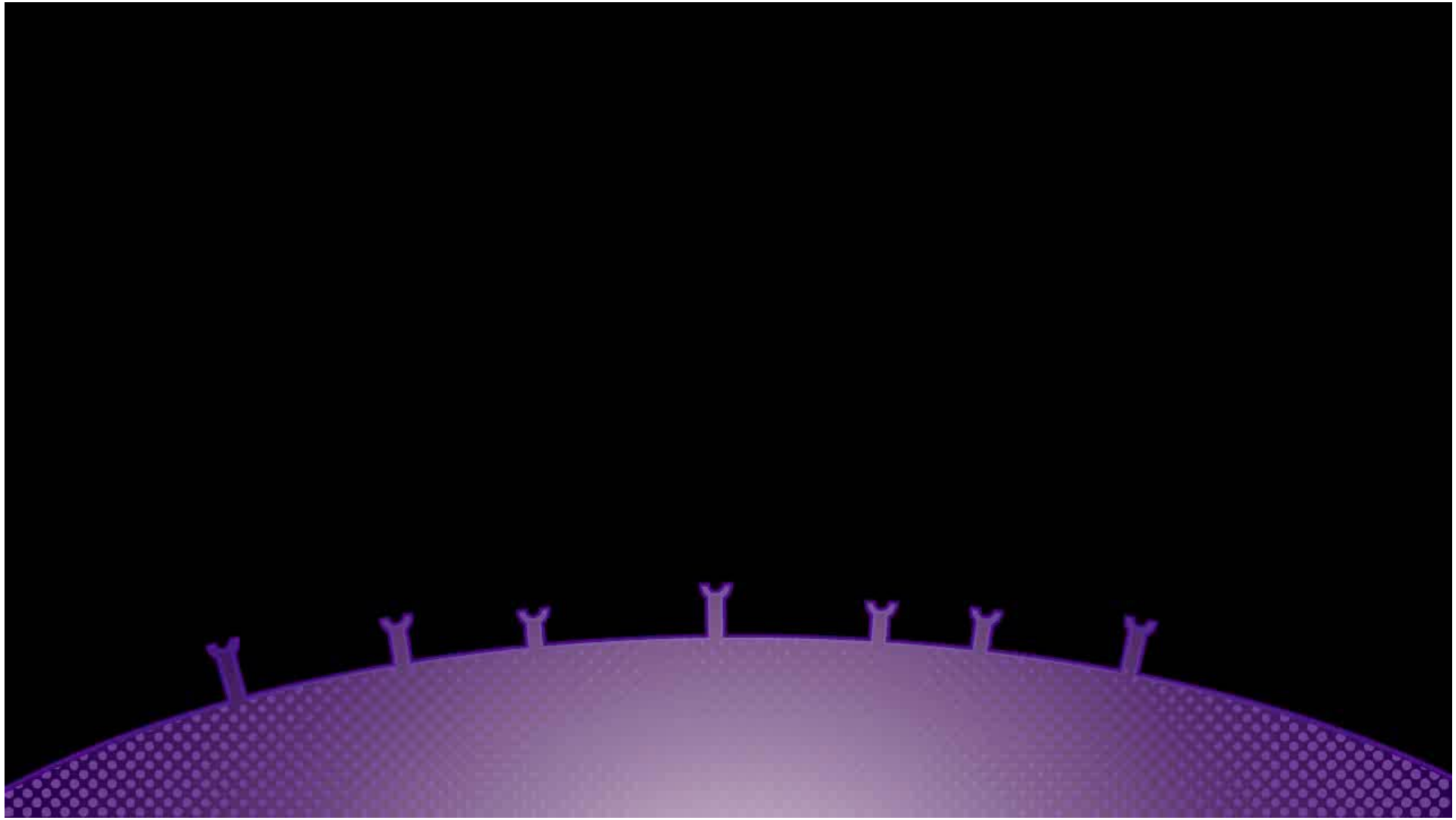


How Do Antibodies Prevent Infection?

1st way: Neutralization

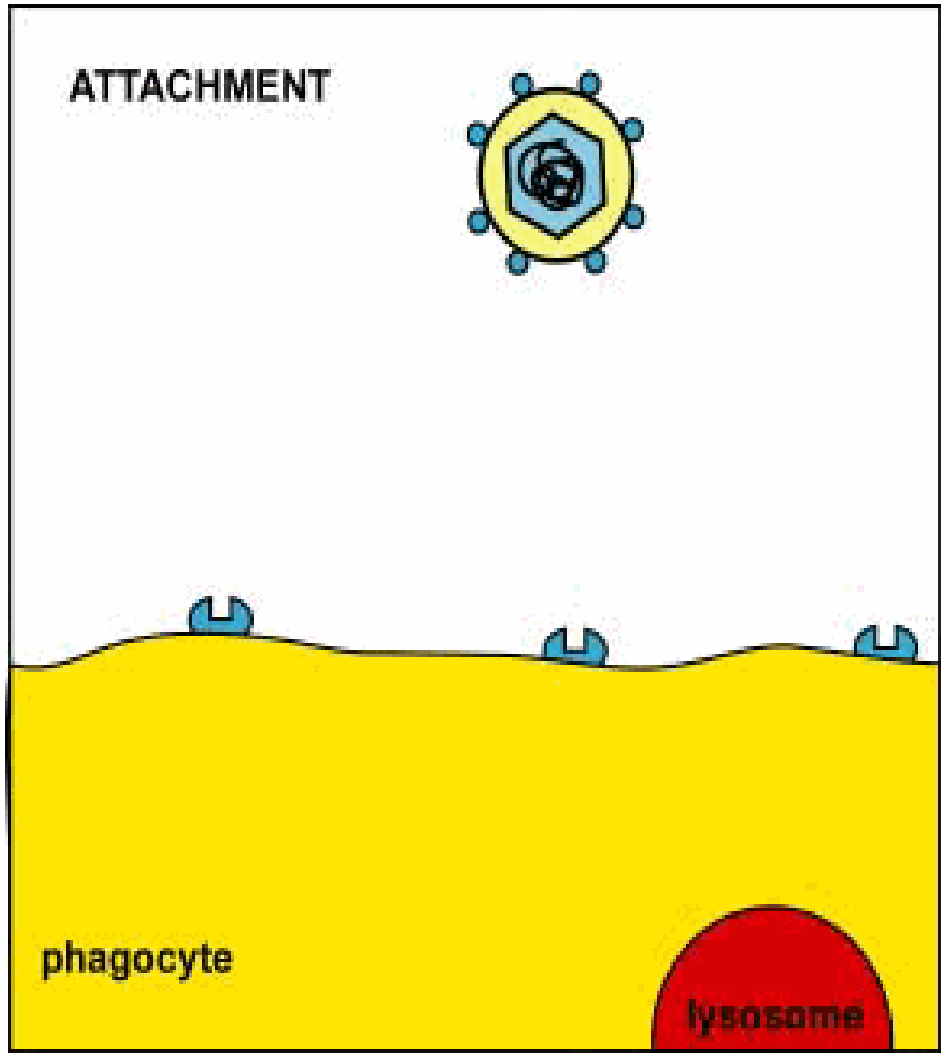


Neutralizing Antibodies Preventing HIV Infection



How Do Antibodies Prevent Infection?

2nd way: Eliminate the virus



Opsonization uses other cells of the immune system to destroy HIV

Binding antibodies sensitize the immune system

Antibody **D**ependent **C**ellular **C**ytotoxicity (ADCC)

- **NK cells may also be able to act like a CD8 killer T cell (“a hitman”)**
- **They need a binding antibody attached to the HIV to act like a “lookout”**
- **With the lookout in place, the NK cell can identify HIV and kill it**

Humoral Response – Summary

- Antibodies attach to the virus at sites that are used by the virus for entry into cells.
- Neutralizing antibodies can work alone to block a virus from entering cells.
- Vaccines designed to elicit neutralizing antibodies against HIV have not worked very well in trials so far.
- Recent discoveries of several broadly neutralizing antibodies are very exciting, and designing a vaccine to produce these antibodies is underway!
- Binding antibodies can attach to HIV and call other parts of the immune system into action to help destroy it.


CD8
CD4
"Helpers"
CELLULAR
ADAPTIVE
HUMORAL
B-CELLS
Antibodies
Dendritic
BOTH
INNATE
Epithelial
Cells
Macrophages
Complement
System
Cytokines
NK cells

Adaptive Part Two - Cellular

- **Cellular response involves two types of cells:**
  - **1) Helper T lymphocytes ($CD4^+$)**
  - **2) Cytotoxic T lymphocytes (CTL or $CD8^+$)**
- **Have memory!**
- **Activated once infection occurs**

The Two Types of Cells

- **$CD4^+$ cells recognize HIV and help cells communicate with each other, calling the killers into action**

- **$CD8^+$ cells are the killers**

How Does the Adaptive Response Work?

- T-cell function: immunosurveillance
- Checks other cells of the body (are they infected or abnormal?)
- Destroys infected or abnormal cells

CD8 Cells May Need Binding Antibodies – More sensitization!

Antibody Dependent Cell-mediated Viral Inhibition

- CD8 cells may also be able to do a better job of killing if they have an antibody acting as the “lookout”
- Their role is already to kill infected cells, but having the antibody in place amplifies their success

Adaptive Response – Summary

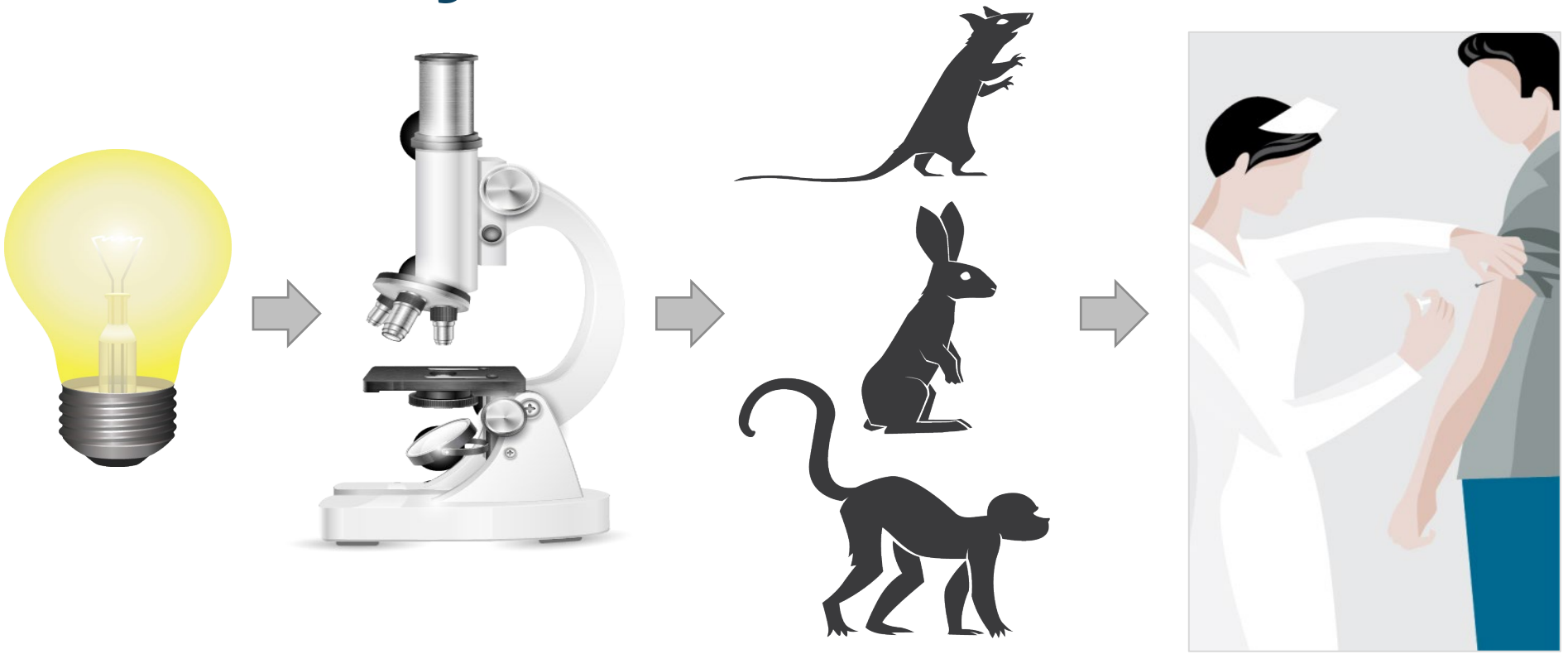
Cellular = Cytotoxic T lymphocytes (CTL or CD8+) and helper T lymphocytes (CD4+)

- **Cannot prevent infection**
- **T cells are activated when cells become infected**
- **T cells can eradicate an established infection**
- **T cells have immunological memory**
- **T cells can be primed by vaccination**

How We Develop And Test Vaccines

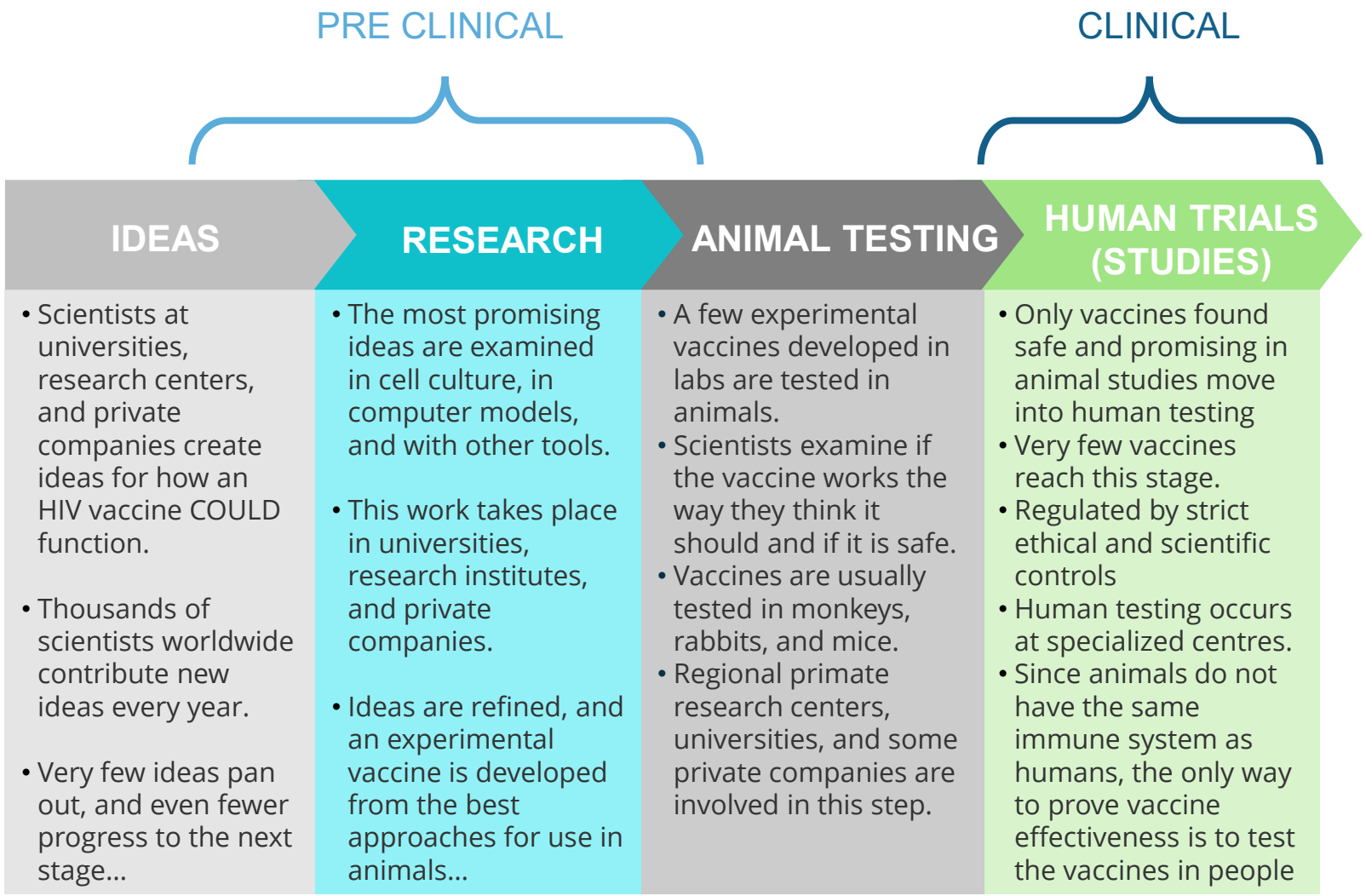
HIV VACCINE
TRIALS NETWORK

How do you test an HIV vaccine?



IDEAS → RESEARCH → ANIMAL TESTING → HUMAN TRIALS (STUDIES)

Stages of Vaccine Development



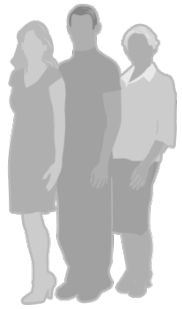
HIV VACCINE TRIALS NETWORK

Stages of Clinical Trials

PHASE I

12 to 18 months

Small group of healthy, HIV negative participants to test safety



PHASE II

Up to 2 years

Hundreds of HIV negative participants to test safety and immune responses, seek best dose or best schedule of administration

PHASE IIb

2-5 years

Several thousand participants at risk for HIV infection to test for safety, immune responses, and to get a first look at efficacy. Tests the concept, and results inform whether to go to Phase III.

PHASE III

3 to 4 years

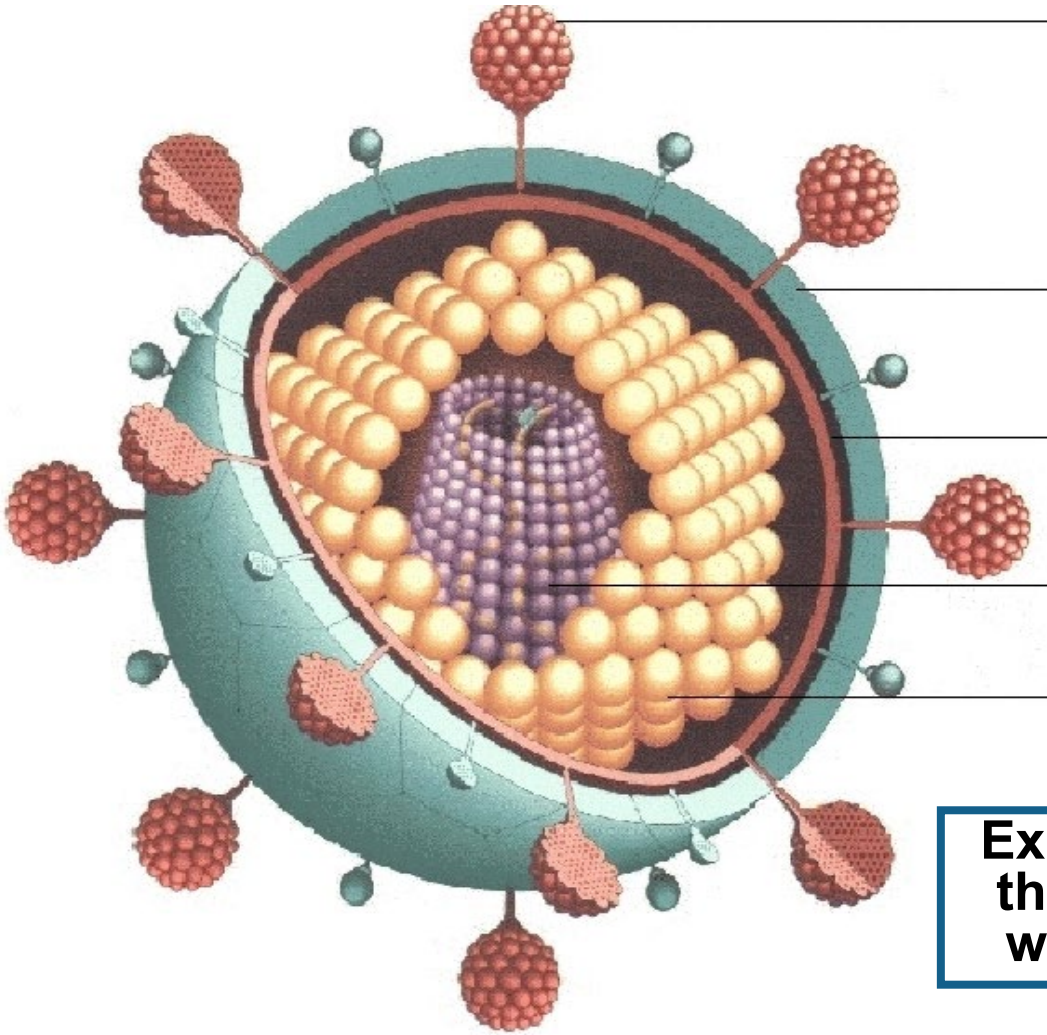
Many thousands of participants at risk to test safety and efficacy

Designing HIV Vaccines

Variables in HIV Vaccine Development

- **Vaccine modality:** whole killed, attenuated, DNA, peptide, recombinant proteins, VLPs, viral vectors (vaccinia, MVA, VSV, Ad, HSV, canarypox, etc.), chimeras
- **Gene(s):** *env, gag, tat, nef, rev, pol, vif, vpu, vpr,* mosaics
- **Adjuvant:** alum, cytokines, MF-59, GM-CSF, etc.
- **Dose**
- **Route:** intradermal, intramuscular, etc.
- **Timing:** how many injections, how far apart
- **Methods of administration:** needle and syringe, Biojector, using electroporation, etc.

HIV Viral Structure



Proteins on the viral envelope (e.g. gp120)

Membrane or envelope (env)

Matrix proteins

Nucleus (genes) (e.g., Gag, Pol, Nef, Tat)

Core proteins (e.g. p24, p17)

Experimental vaccines tested in the HVTN today do *not* include whole, killed or weakened HIV

HIV VACCINE TRIALS NETWORK

Thinking About the HIV Inserts

What Carries the HIV Inserts?

Vectors: A vector is the “carrier” that “delivers” the HIV inserts to your body’s immune system.

Making the “Vaccine Sandwich”

What if your vaccine needs a little “something extra” to give it more strength?

Adjuvants


Peri-Peri
HOT sauce
LOUISIANA
THE PERFECT
HOT SAUCE
ONE DROP DOES IT
NET 12 FL OZ (354 mL)
TEXAS PETE
Hot Sauce
NET WT. 12 OZ. 340g
MADE IN U.S.A.
McILHENNY CO.
AVERY ISLAND, LA.
TABASCO
BRAND
EST. 1868
PEPPER SAUCE
CRACKED
PEPPERCORN
A.1.
STEAK SAUCE
CRACKED
PEPPERCORN
NET WT 10 OZ (283g)
SINCE 1904
French's
SINCE 1904
WORCESTERSHIRE
SAUCE
Extra Tenderizing

How Vaccines Work

HIV VACCINE
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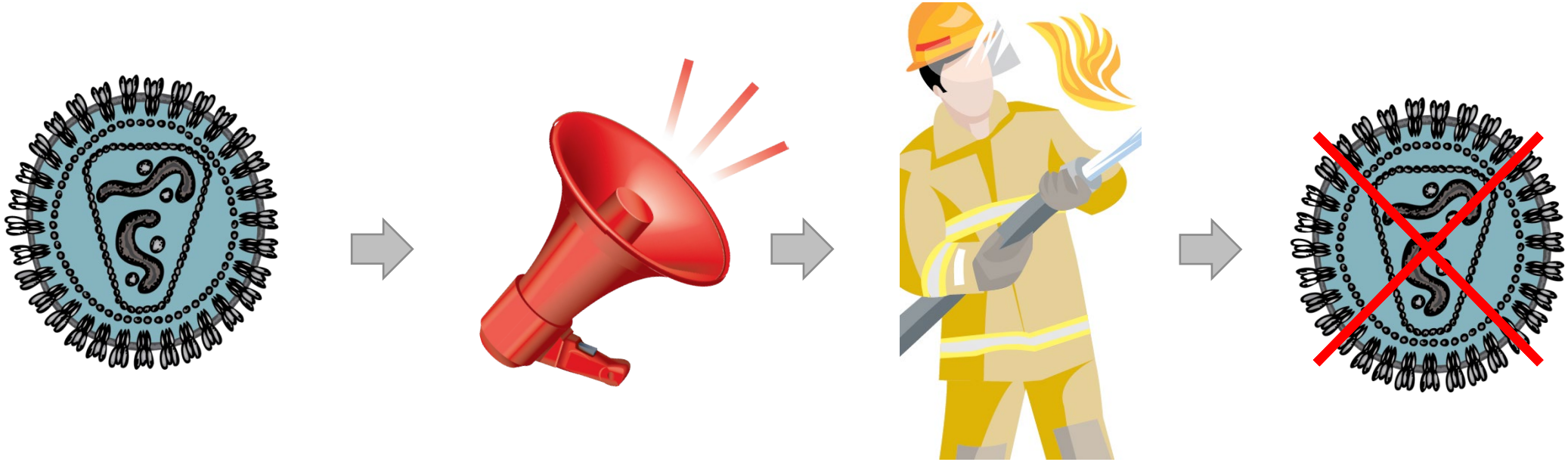
How does a vaccine work?

By teaching the body to recognize and fight invaders



Body recognizes HIV

Body –
sounds alarm

Fighter cells & proteins
go into action

GOAL – HIV is
killed or controlled

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Using new vaccine technologies

- Common vaccines such as chickenpox or flu use the whole or weakened form of the virus.
- Other vaccines, such as Hepatitis B, use only pieces of the virus.
- *The study vaccines we are testing are different.* There is no real HIV in our study vaccines. The study vaccines are made in a laboratory.

Can HIV vaccines give someone HIV?

NO!

The HIV vaccines being tested are made from synthetic (laboratory made) pieces of HIV. Therefore, the vaccines CANNOT cause HIV infection.

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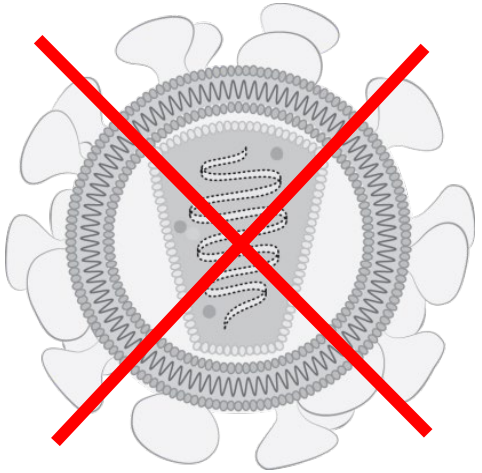
Acknowledgments: Bridge HIV/SFDPH

Study vaccines do not cause HIV!

- There is no actual HIV in the study vaccines.
  They *cannot* give you HIV.

- But we don't know if the vaccines will decrease ↓, increase ↑, or not change = your chance of becoming infected with HIV, if you are exposed to the virus (through behavior).



So please continue to protect yourself!

Use condoms

Reduce number of partners

PrEP also recommended where appropriate!

HIV VACCINE TRIALS NETWORK

Acknowledgments: Bridge HIV/SFDPH

Study Vaccines

- The **study vaccines** are experimental. We have some information on their safety in people, but we don't yet know if they will prevent HIV infection.
- The **study vaccines** can only be used in research.

Safety Monitoring

- Safety is monitored by 2 groups:
  - Safety Review Team (SRT): this group of doctors, scientists, and nurses who work on the study team review information about participant safety every 2 weeks. They do not know whether the participant got the vaccines or the placebo.
  - Data Safety Monitoring Board (DSMB): this group of independent experts meets every 6 months to review study data. They are informed about who got the vaccines or the placebo. They are not part of the study team.
- The DSMB can permanently stop the study if they feel that participants could be harmed.

Rights and Responsibilities

- You have rights and responsibilities if you join this study.
- We list these in the Participants' Bill of Rights and Responsibilities.

PARTICIPANTS' BILL OF RIGHTS AND RESPONSIBILITIES

RIGHTS

As a participant in an HIV Vaccine Trials Network study, you have the right to:

- **Have all known information, including potential risks and benefits of trial participation, presented to you in a way in which you can understand.** You will be told about any new information learned during the course of the study.
- **Refuse to join the study or decide to leave the study at any time.** You can also refuse to join any follow-up studies you are told about. You will not lose any of the rights referred to in this document if you refuse to join the study or leave the study.
- **A discrimination-free study environment.** Your personal choices, values, beliefs, and cultural context will be respected by the people running the study.
- **Referral to available counseling and support services for issues related to the study and HIV prevention.**
- **Referral to available counseling, support, medical, and treatment services for illnesses you suffer during the study, including HIV.**
- **Assistance resolving study-related social problems and/or discrimination.** With your permission, we can talk to the people you ask us to contact to explain more about your participation in the study.
- **Treatment for physical injuries, should they occur, for any injury more likely to be related to study products or procedures than to any other cause, to the extent described in the study consent form.** There are funds to pay for treatment of these injuries. A group that reviews safety issues for the study makes the determination of relatedness. You can have the decision reviewed if you disagree. In some cases, the funds may not be enough to cover full treatment. The groups involved in the study will seek more funds if needed, but cannot guarantee them. Your study staff will provide more information on this issue and will answer any questions you may have or put you in touch with the person most qualified to answer your questions.
- **Free and accurate testing for HIV infection during the study.** If, at the end of the study, you have a positive HIV test that is caused by the study vaccine and not by HIV infection, you can receive follow-up testing at the study clinic until the test becomes negative.
- **Assistance in meeting study commitments.** A list of the items that are available to you will be provided by your study site.
- **Confidentiality.** Communications and records about you and your participation in the study will be shared only as needed to conduct the study, or as required by law. See your study site's informed consent form for more information.
- **Be offered a study identification card that shows that you are in the study.** This optional card will include the phone number and/or address of a person who can provide additional information.
- **Maintain your legal rights.** As a trial participant, you are not waiving any of your rights.
- **Be told whether you received a placebo or a vaccine when the study ends, or when medically necessary.**
- **Be updated about progression of studies, told when study results may be available, and told how to learn about the results.**

RESPONSIBILITIES

As a participant in an Hiv Vaccine Trials Network study, you have the responsibility to:

- **Review and demonstrate an understanding of all the materials given to you, including the informed consent documents.** Ask for explanation about any information you do not understand before you agree to participate in the study. You can also ask questions anytime during the study.
- **Make an informed decision about whether to participate in this study after weighing the risks and benefits.** It is important to know what the study is about. The staff will assist you in this. If it helps you to make a decision, talk to people you trust and respect about whether joining the study is right for you.
- **Tell study staff as soon as possible if you experience discrimination and/or social harm that you think may be related to your trial participation.**
- **Do not give blood or donate organs or other body fluids during the study.**
- **Get your HIV testing done only at the study site as long as the study lasts.** Talk to the study staff if you have to get tested elsewhere.
- **If you are able to get pregnant, avoid pregnancy during the study by using effective birth control methods.** The staff will review effective birth control methods with you.
- **Keep your study appointments.** Tell study staff as soon as possible if you need to reschedule an appointment.
- **Treat study staff with respect.**
- **Keep confidential the participation of others in the study.**
- **Give the study staff complete and accurate study-related information.** Tell the study staff about any changes in your contact information or health information.
- **Follow the instructions of the study staff to the best of your ability.** Work together with the study staff to maintain your health and safety during the trial.
- **Tell study staff as soon as possible if you are unable to continue or if you decide to stop your study participation.**

To view the Participants' Bill of Rights and Responsibilities in other languages please visit hvtn.org/en/participants/participants-rights.html

HIV VACCINE TRIALS NETWORK

Global Community Advisory Board (GCAB)

Sibusiso Mngadi

GCAB co-chair, Durban, South Africa

Coco Alinsug

GCAB co-chair, Boston, US

- At least one local CAB representative from every site sits on the GCAB
- At least one CAB representative sits on every protocol team
- CAB representation on key scientific committees

➢ GCAB ensures that the global voice of the public is heard

HIV VACCINE TRIALS NETWORK

Lessons Learned From COVID-19

HIV VACCINE
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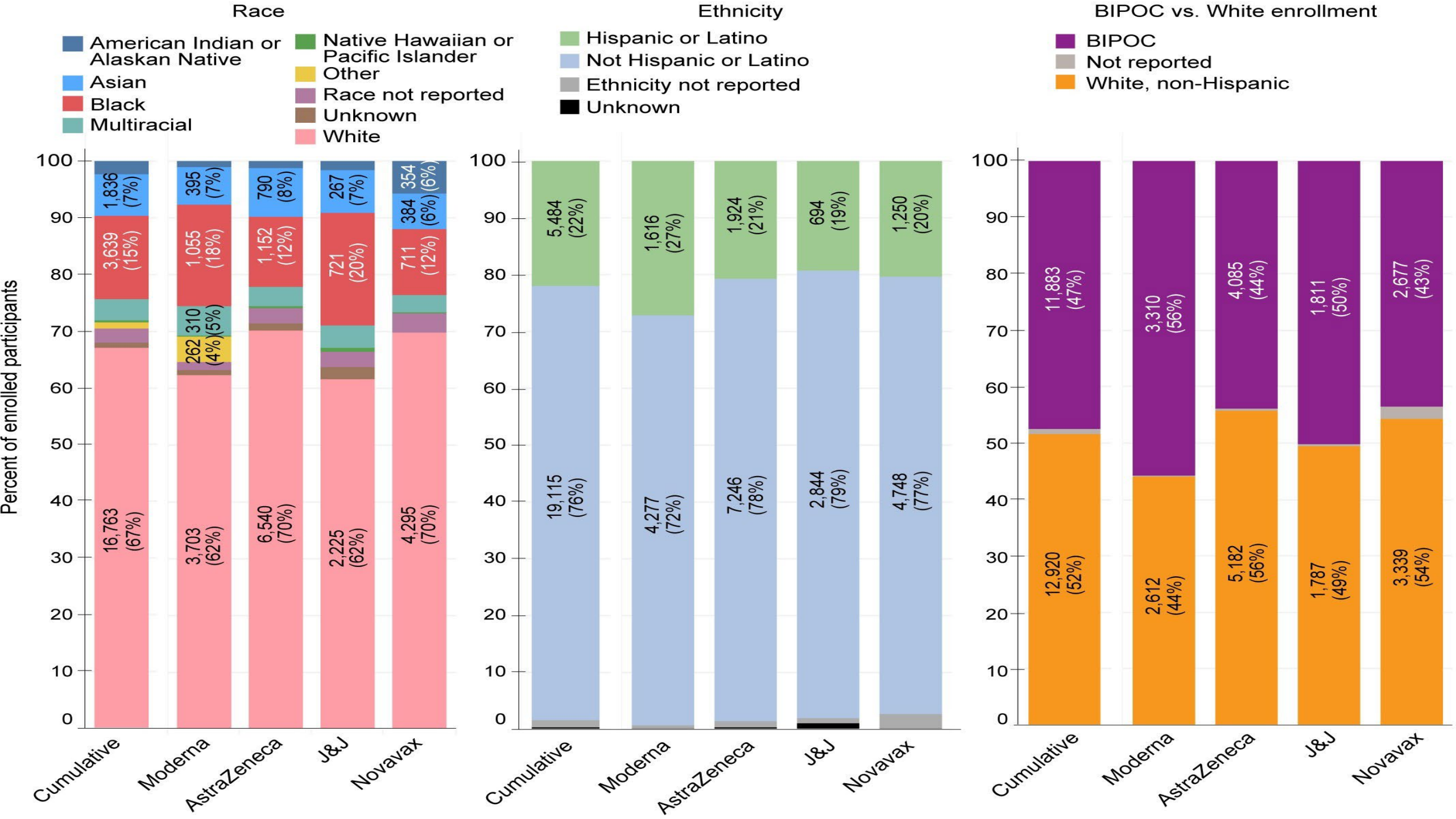
HOW DID WE GET TO PHASE 3 SO QUICKLY?

Usually when this effort is undertaken by individual pharmaceutical companies, they start production when all hurdles have been cleared and government reviewers have seen the results of all phases of the study and evaluated effectiveness.

For COVID-19, the US Government began investing billions of dollars to start producing vaccines after early study phases, and are reducing the bureaucracy that usually holds up review of later phase results, cutting significant amounts of time, without cutting corners.


Race
American Indian or Alaskan Native
Asian
Black
Multiracial
Native Hawaiian or Pacific Islander
Other
Race not reported
Unknown
White
Ethnicity
Hispanic or Latino
Not Hispanic or Latino
Ethnicity not reported
Unknown
BIPOC vs. White enrollment
BIPOC
Not reported
White, non-Hispanic
Percent of enrolled participants
100
90
80
70
60
50
40
30
20
10
0
1,836 (7%)
3,639 (15%)
16,763 (67%)
395 (7%)
1,055 (18%)
310 (5%)
262 (4%)
3,703 (62%)
790 (8%)
1,152 (12%)
6,540 (70%)
267 (7%)
721 (20%)
2,225 (62%)
354 (6%)
384 (6%)
711 (12%)
4,295 (70%)
5,484 (22%)
19,115 (76%)
1,616 (27%)
4,277 (72%)
1,924 (21%)
7,246 (78%)
694 (19%)
2,844 (79%)
1,250 (20%)
4,748 (77%)
11,883 (47%)
12,920 (52%)
3,310 (56%)
2,612 (44%)
4,085 (44%)
5,182 (56%)
1,811 (50%)
1,787 (49%)
2,677 (43%)
3,339 (54%)
Cumulative
Moderna
AstraZeneca
J&J
Novavax

CoVPN External Relations & Social Media Engagement Report

Report Details

- **Time Frame:** August December 2020
- **Events covered:**
  - COVID in Black Series
  - Pandemia Series
  - COVID in Color
  - Iman & COVID
  - Making it Plan with Dr. Fauci
  - The COVID 19 Fear Factor
  - Souls, Storms and Science
- **Social channels:**
  - Instagram: @preventCOVID19
  - Facebook: @PreventCOVID19
  - Twitter: @PreventCOVID_19

Performance Recap

Total Reach:
2,625,865
Organic: **94,059**
Paid: **2,531,806**

Total Impressions:
6,509,790
Organic: **120,179**
Paid: **6,389,611**

Total Engagements:
117,072
Organic: **10,889**
Paid: **106,183**

Total Posts:
86
Organic: **79**
Paid: **7**

Platform Breakdown

FACEBOOK ORGANIC
Total Posts: **36**
Total Reach: **55,385**
Total Impressions: **60,226**
Total Engagements: **9,495**

FACEBOOK PAID
Total Posts: **7**
Total Reach: **2,531,806**
Total Impressions: **6,389,611**
Total Engagements: **106,183**

INSTAGRAM ORGANIC
Total Posts: **22**
Total Reach: **16,637**
Total Impressions: **19,732**
Total Engagements: **942**

TWITTER ORGANIC
Total Posts: **21**
Total Reach: **22,037**
Total Impressions: **40,221**
Total Engagements: **452**

Reach represents the number of people who saw the post; Impressions represents how many times the post was seen – some people may have looked at it more than once. Engagement represents the number of times people interacted with the post – commenting or liking, etc.

Organic impressions are the number of unique people who saw content for free in a newsfeed. Paid impressions are the number of unique people who saw content as the result of a paid social media ad.

HIV VACCINE TRIALS NETWORK

HIV Vaccine Approaches in COVID-19 Vaccine Development

Vaccine approaches orginally developed for HIV vaccine design are at the forefront of COVID-19 vaccine development. There are over 100 vaccine candidates in development against COVID-19, many of the vaccines and approaches in human trials have roots in HIV research. Below are some of the approaches moving forward in human trials.

Antibodies

The AMP trials, with results due in October, are now testing infusions of an HIV-neutralizing antibody every two months as a prevention method. Antibody approaches like this, including convalescent plasma, and neutralizing antibody infusions and injections, are being developed for both prevention and treatment of COVID-19.

Chimp adenovirus vector

A vaccine developed at Oxford University from a virus that infects chimpanzees is being developed for therapeutic and preventive clinical trials against HIV and a number of other diseases. That chimpanzee virus platform has been adapted as a COVID-19 vaccine candidate and is now in clinical trials.

DNA

HIV vaccine approaches using a DNA platform are now being explored for COVID-19. Inovio has begun testing its DNA vaccine platform, originally developed for HIV vaccines, for use as a COVID-19 vaccine.

Human adenovirus vectors

Multiple adenovirus subtypes have been developed as HIV vaccine candidates, most notably, Janssen's Ad26 candidate, which is now in two large HIV vaccine efficacy trials. Janssen is now adapting its Ad26 as a COVID-19 vaccine. There are also several other adeno-based COVID-19 vaccines in development, such as the Ad5 adenovirus being tested by the Chinese military.

mRNA

Messenger RNA (mRNA) vaccines, potentially more potent than DNA platforms, have been developed as HIV vaccine candidates. Now, several mRNA vaccine candidates against COVID-19 are in clinical trials sponsored by Moderna, CureVac and Pfizer/BioNTech.

AVAC
25 Years and Counting

May, 18 2020
avac.org

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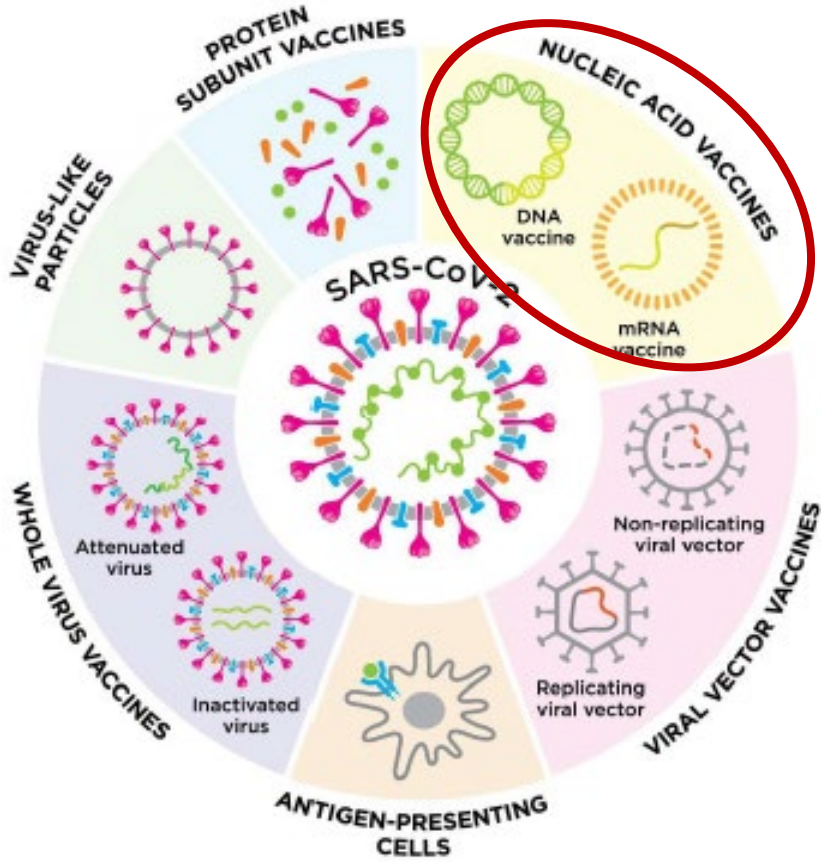
Leverage/Expand on Success Achieved during the COVID-19 Pandemic



- RNA and DNA-based platforms
  - Safe
  - Rapid, scalable and low-cost manufacturing
  - Allows rapid iterative testing and optimization concepts
  - Versatile – diversity and multiplicity of inserts: broad coverage
  - Self-adjuvanted and immunogenic
  - Prolonged immunogen expression
  - Induce and boost cellular, humoral, and innate immunity
  - Tfh to support germinal centers for development of memory/plasma cells

External Relations

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Thank you!

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