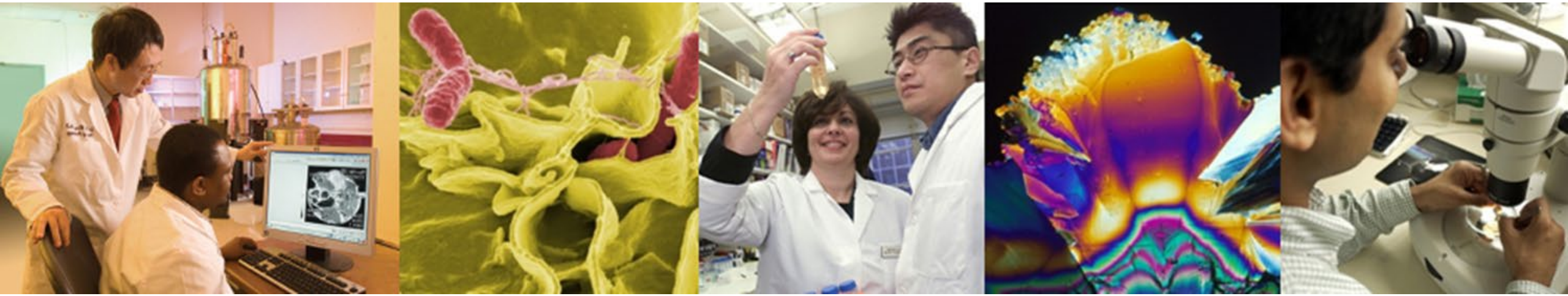
NIH Update

Council of Councils Meeting
January 29, 2021



Lawrence A. Tabak, DDS, PhD
Principal Deputy Director, NIH
Department of Health and Human Services

Topics for Today

- NIH Budget Update
- Update on the Presidential Transition
- COVID-19 Update
- The UNITE Initiative

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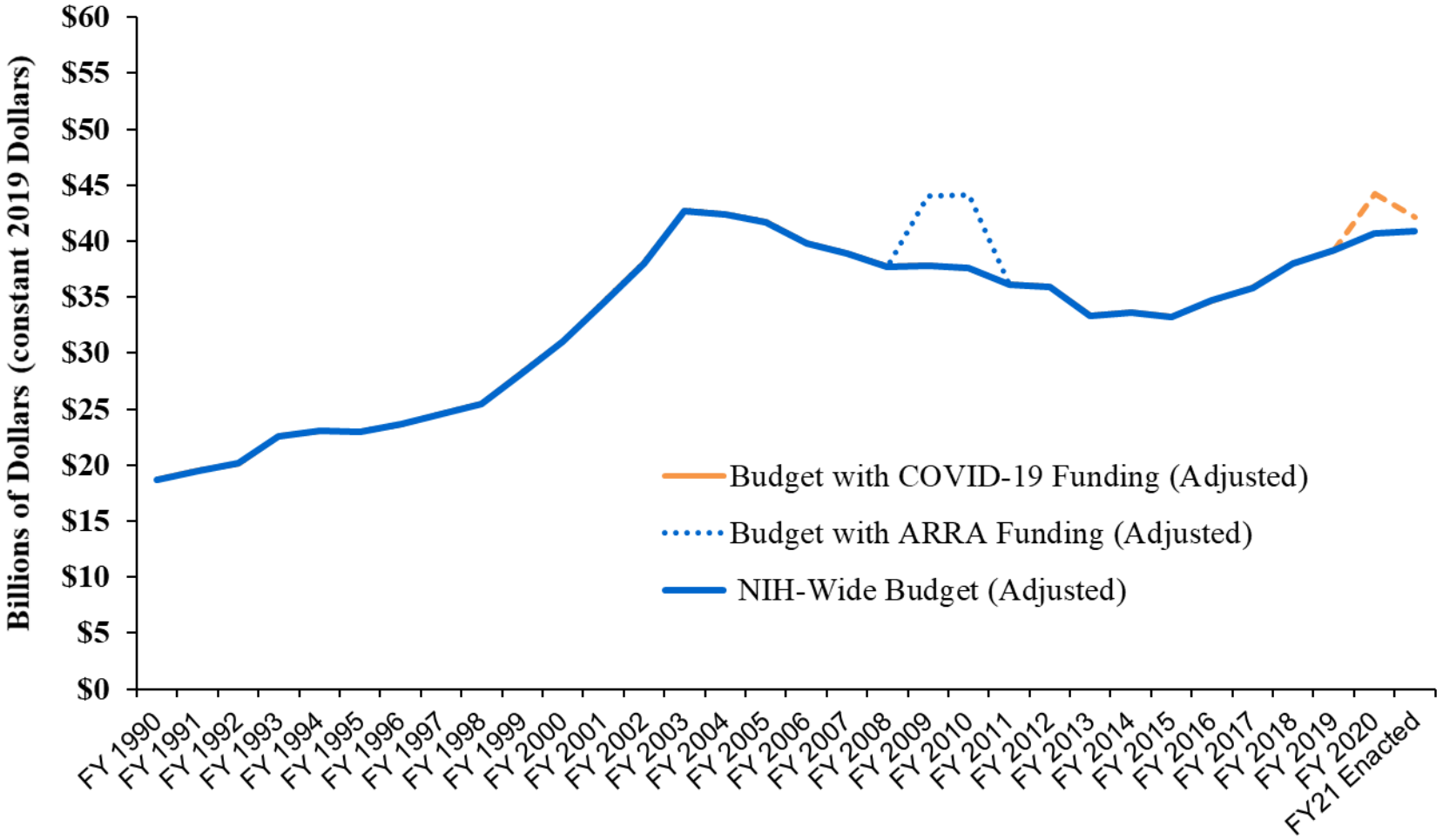
National Institutes of Health Funding
1990-2021



Note: Dollar values are adjusted to 2019 dollars using the Biomedical Research and Development Price Index (BRDPI), http://officeofbudget.od.nih.gov/gbiPriceIndexes.html

Source: NIH Office of Extramural Research and Office of Budget source data (January 2019 - January 2020).

CURES Funding

Program	Increase	Total
All of Us		
OD	*40*	*391*
Cures	*-40*	*109*
Total	**0**	**500**
BRAIN		
ICs	*100*	*460*
Cures	*-40*	*100*
Total	**60**	**560**
Cancer Moonshot	**195**	**195**
Regenerative Medicine	**-8**	**0**
BRAIN increase/decrease is split equally between NINDS and NIMH		

Specific Increases

- Requested by NIH:
  - Expand ML-focused Grants $50 million (OD)
  - Ending the HIV Epidemic $10 million (NIAID)
  - Premature Birth $10 million (NICHD)
  - Gene Vector Production $10 million (NCATS)
  - Lyme & Other Tick-Borne Diseases $10 million (NIAID)
- Alzheimer's disease $300 million (NIA)
- Chronic Diseases & Health Disparities $45 million (NIMHD)
- Regional Biocontainment Labs $40 million (NIAID)
- NCI Paylines $37.5 million (NCI)
- Office of Data Science Strategy $25 million (OD)
- Universal Flu Vaccine $20 million (NIAID)

Emergency Supplemental Funding

- NIH received an additional $1.25 billion to prevent, prepare for, and respond to coronavirus, all in the OD account
- Funds are available for obligation through FY 2024
  - $1.15 billion is for research and clinical trials related to long-term studies of COVID
  - $100 million is for RADx

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Science in the Biden Administration

Designates

Xavier Becerra

SECRETARY OF HEALTH AND HUMAN SERVICES

Dr. Eric Lander

PRESIDENTIAL SCIENCE ADVISOR AND DIRECTOR OF THE OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Francis S. Collins, MD, PhD

Francis S. Collins remains the Director of NIH. He is the 16th NIH Director and the only person to have served in more than one administration.

Rochelle P. Walensky, MD, MPH

Rochelle P. Walensky, MD, MPH, is the 19th Director of the Centers for Disease Control and Prevention and the ninth Administrator of the Agency for Toxic Substances and Disease Registry.

Biden Health Team

WH

- **Anthony Fauci, Chief Medical Advisor**
- **Carole Johnson, COVID-19 Testing Coordinator**
- **David Kessler, Vaccine Chief**
- **Marcella Nunez-Smith, COVID-19 Equity Task Force Chair**
- **Jeff Zients, COVID-19 Response Coordinator**

HHS

- **Rachel Levine*, ASH**
- **Vivek Murthy*, Surgeon General**

*Indicates Designate Status

Science Leads the Way

January 15, 2021

Eric S. Lander, Ph.D.
President and Founding Director
Broad Institute of MIT and Harvard

Dear Dr. Lander:

In 1944, President Franklin D. Roosevelt authored a letter to his science advisor, Dr. Vannevar Bush, posing the question of how science and technology could best be applied to benefit the nation's health, economic prosperity, and national security in the decades that would follow the Second World War. Dr. Bush's response came in the form of a report, titled *Science—the Endless Frontier*, that would form the basis of the National Science Foundation and set the course of scientific discovery in America for the next 75 years.

- What can we learn from the pandemic about what is possible—or what ought to be possible— to address the widest range of needs related to our public health?
- How can breakthroughs in science and technology create powerful new solutions to address climate change—propelling market-driven change, jump-starting economic growth, improving health, and growing jobs, especially in communities that have been left behind?
- How can the United States ensure that it is the world leader in the technologies and industries of the future that will be critical to our economic prosperity and national security, especially in competition with China?
- How can we guarantee that the fruits of science and technology are fully shared across America and among all Americans?
- How can we ensure the long-term health of science and technology in our nation?

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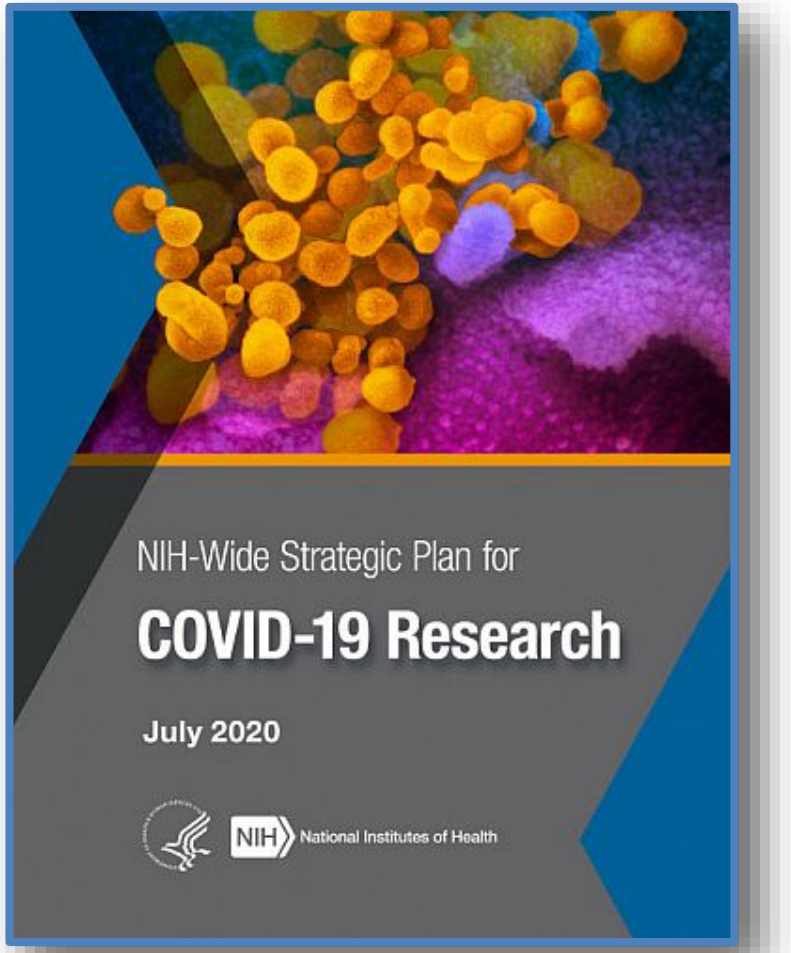
NIH-Wide Strategic Plan for COVID-19 Research

- Provides a framework for five strategic priorities:
  - Invest in NIH and NIH-funded researchers to **increase knowledge** of SARS-CoV-2 and COVID-19
  - Speed innovation in **COVID-19 testing technologies**
  - Forge groundbreaking approaches that speed identification, development, evaluation, and manufacturing of **promising candidate therapeutics**
  - Support studies on preventative treatments and behavioral and community **prevention practices, including vaccines**
  - Ensure that diagnosis, treatment, and prevention options are **accessible and available for underserved and vulnerable populations**



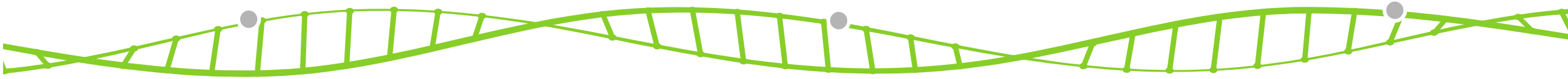
Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

ACTIV is being coordinated by the Foundation for the National Institutes of Health (FNIH), and has brought together multiple partners from government, industry and non-profits.

8
Government Partners

20
Industry Partners

4
Non-Profits



BARDA
CDC
Department of Defense
European Medicines Agency
U.S. Food & Drug Administration
Operation Warp Speed
NIH
Department of Veterans Affairs

abbvie
AMGEN
AstraZeneca
Bristol-Myers Squibb
dewpointx
Eisai
Lilly
gsk
Johnson & Johnson
MERCK
moderna
NOVARTIS
RHYTHM THERAPEUTICS
Roche Genentech
Pfizer
SANOFI
Takeda
NOVAVAX
VIR

Bill & Melinda Gates Foundation
Fred Hutch Cures Start Here
RTI International
FNIH

ACTIV Fast-Track Focus Areas | Objectives & Composition

The ACTIV partnership consists of four fast-track focus areas (Working Groups) with membership of both public and private sector representatives to oversee tactical operations :

	Vaccines	Preclinical	Clinical Trial Capacity	Therapeutics – Clinical
Objective	+ Accelerate the evaluation of vaccine candidates to enable rapid authorization or approval	+ Develop a collaborative, streamlined forum to identify preclinical treatments	+ Improve clinical trial capacity and effectiveness	+ Accelerate clinical testing of the most promising COVID treatments
Sub-Groups	+ Vaccines Clinical Trials + Protective Immune Responses + Vaccine-Associated Immune Enhancement	+ Animal Models + In Vitro Assays + Mutation Tracking	+ Survey Development + Clinical Trial Network Inventory + Innovations	+ Agent Prioritization + Master Protocol

Current Portfolio of ACTIV Master Protocols

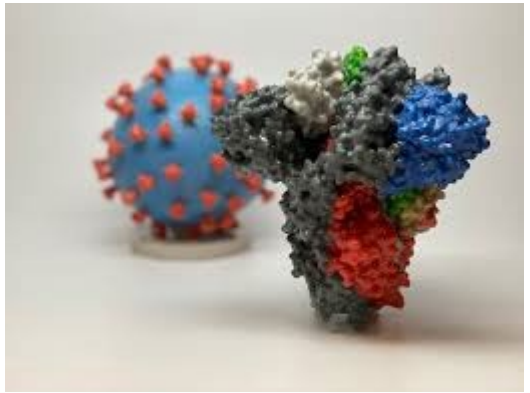
ACTIV Therapeutics has been taking a portfolio approach to address the dramatic health and economic challenges posed by the pandemic, with harmonized "master protocol" trials.

	DESIRED OUTCOMES	STATUS
ACTIV-1	• Phase III trial of 3 host-targeted immune modulators • Inpatient (hospitalized) patient population • NCATS Trial Innovation Network + CRO	• ***Trial launched October 16*** • First 3 agents selected – Abatacept, Infliximab, and Cenicriviroc
ACTIV-2	• Phase II/III trial of up to 5-7 Neutralizing Antibodies and Oral Antivirals • Outpatient population • NIAID ACTG network + CRO	• ***Trial launched August 3*** • Initial agent: nAb from Lilly; onboarding other agents
ACTIV-3	• Phase III trial of 5-7 Neutralizing Antibodies and Oral Antivirals • Inpatient population • NIAID INSIGHT + NHLBI PETAL + NHLBI CSTN + VA networks +CRO	• ***Trial launched August 4*** • Initial agent: nAb from Lilly (halted for futility Oct. 26); onboarding other agents • Preliminary results submitted to NEJM on Nov 9
ACTIV-4	• Phase III trial of anticoagulants (heparin, aspirin) and antiplatelet drug • Three different populations: pre-hospitalized, hospitalized, & post-hospitalized • NHLBI-NINDS CONNECTS network	• ***Hospitalized & Pre-Hospitalized cohorts launched on Sept 17*** • ***Post-hospitalized cohort launching late January*** • First agents – LMWH and UFH (hospitalized) and low dose aspirin, high dose aspirin, and apixaban (pre-hospitalized) • Enrollment of inpatient patients with heparin halted due to efficacy
ACTIV-5 *(Big Effect Trial)*	• Phase II "proof of concept" study to identify multiple promising treatments • Inpatient population • NIAID networks + CRO	• ***Trial launched October 9*** • Two initial agents selected – Risankizumab + Lenzilumab • Prioritizing additional agents

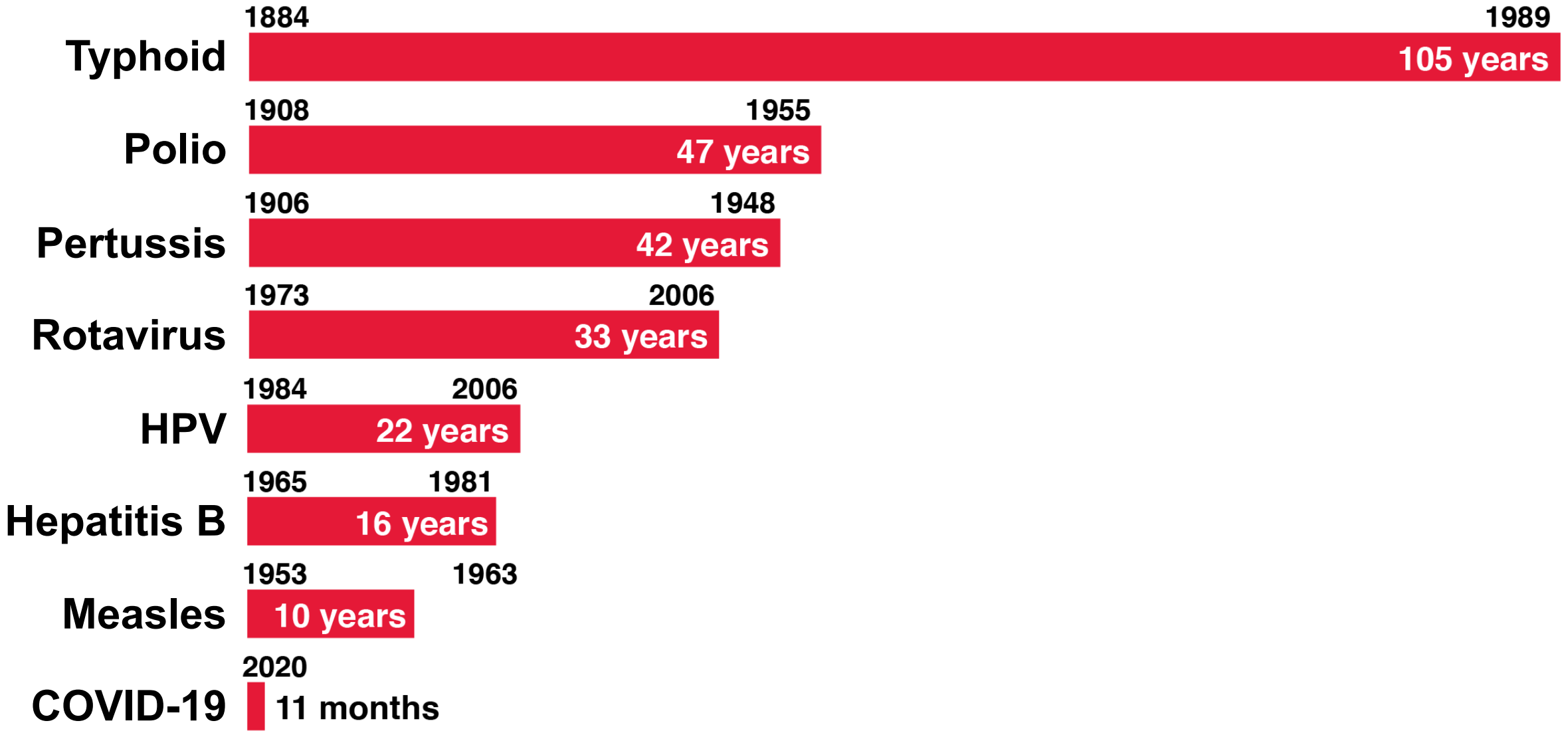
Colchicine Coronavirus SARS-CoV2 Trial

- The Montreal Heart Institute announced today that the COLCORONA clinical trial has provided clinically persuasive results of colchicine's efficacy to treat COVID-19.
- Results have shown that colchicine has reduced by 21% the risk of death or hospitalizations in patients with COVID-19 compared to placebo

NIH COVID-19 Vaccine Response

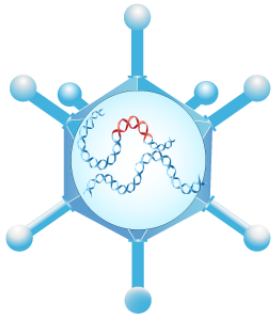
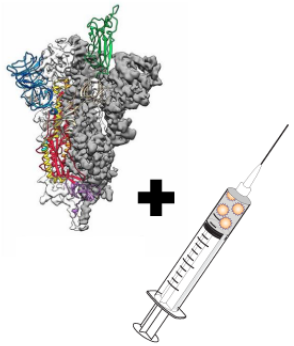


Time to Develop a Vaccine



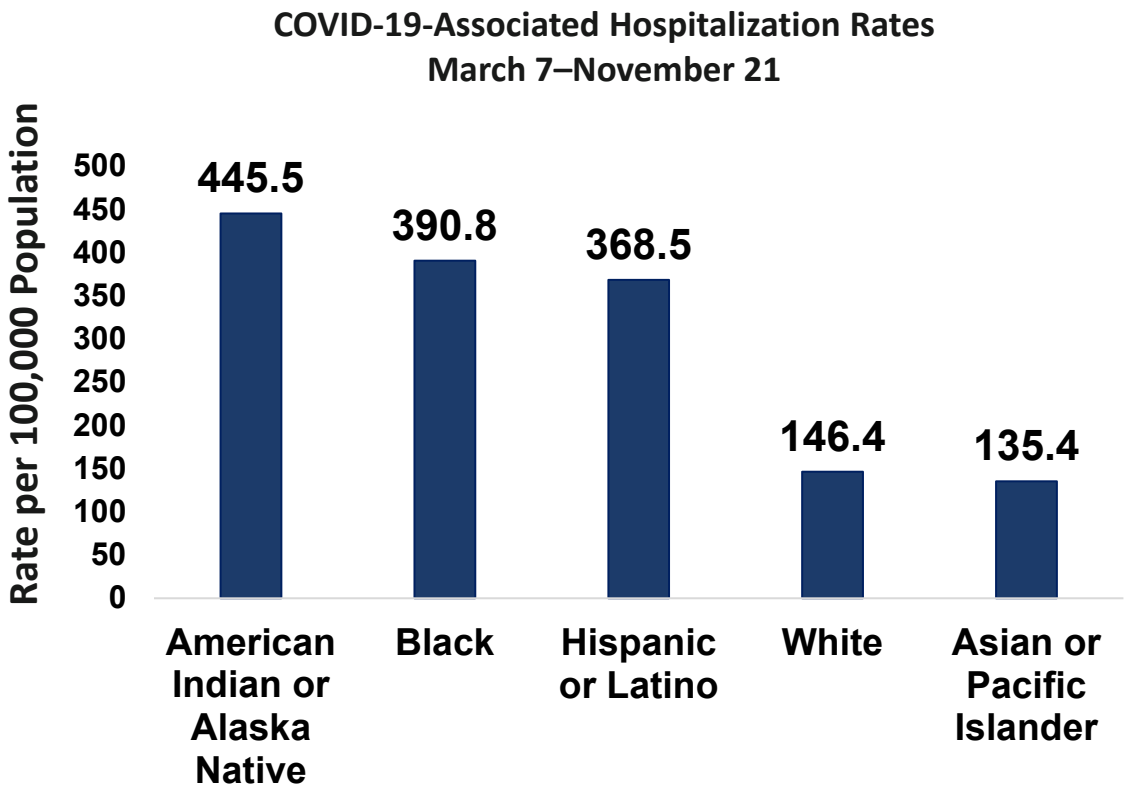
Duration between discovery of microbiologic cause of selected infectious diseases and development of a vaccine. Adapted from AVAC

COVID-19 Vaccines in OWS Development

moderna	**mRNA**	
BIONTECH Pfizer	**mRNA**	
AstraZeneca	**Adenovirus vector**	
janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson	**Adenovirus vector**	
NOVAVAX Creating Tomorrow's Vaccines Today	**Recombinant protein + adjuvant**	
gsk SANOFI	**Recombinant protein + adjuvant**	

- mRNA: **Rapid manufacturing facilitating efficient move to clinic, highly immunogenic**
- USA FDA Emergency Use Authorization
- Adenovirus: **Rapid manufacturing facilitating efficient move to clinic, vaccine using this platform is approved in Europe**
- Adjuvanted recombinant protein: **not as fast to manufacture but scalable, several approved vaccines use this approach**

The COVID-19 Pandemic in the U.S. Disproportionately Affects Communities of Color

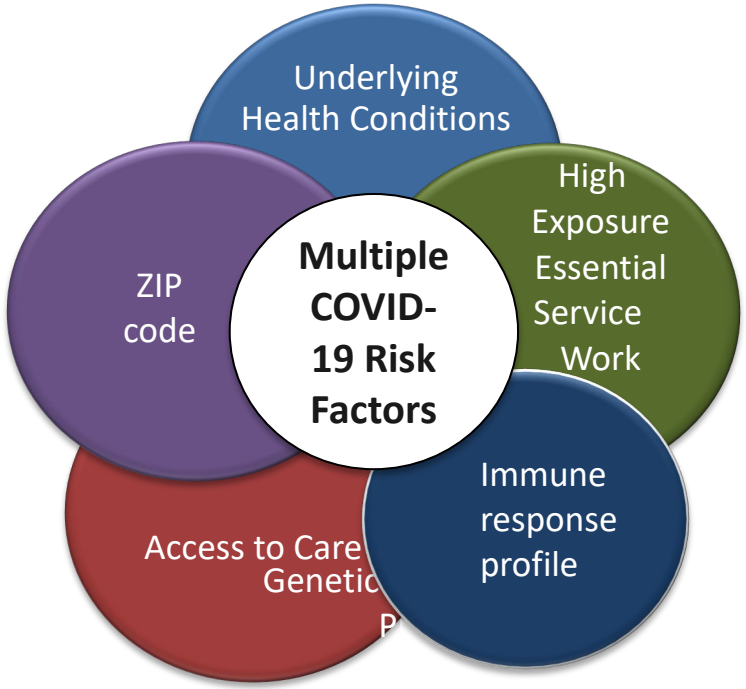


Among some racial and ethnic minority groups, evidence points to higher rates of hospitalization or death from COVID-19 than among non-Hispanic white persons.

COVID-NET

Interplay of clinical characteristics and social determinants of health puts minority communities at high risk for COVID-19 complications

- Heart Disease
- Hypertension
- Diabetes
- Lung Disease



CDC, National Center for Health Statistics (NCHS), National Vital Statistics System, 2019; Yan R, et al., *Science*, 2020.

Addressing a History of Mistrust in Research and Health Care System

"Recruiting Black volunteers for vaccine trials during a period of severe mistrust of the federal government and heightened awareness of racial injustice is a formidable task."
New York Times, October 7, 2020

Black adults are much less likely to say they would get a vaccine than other Americans

- 42% of Black adults (10% increase since Sept.)
- 61% of White adults (9% increase since Sept.)
- 63% of Hispanics (7% increase since Sept.)
- 83% of Asian Americans (11% increase since Sept.)

Trend holds even for those who regularly get a flu vaccine. Of these:

- 33% of Black Adults would not seek COVID-19 vaccine
- 15% of White Adults would not seek COVID-19 vaccine

KFF/The Undefeated Survey on Race and Health

NIH Guiding Principles to Combat COVID-19 through Community Engagement

1. Build and sustain **trusting relationships** through **community engagement.**
2. **Acknowledge social determinants of health's** role in COVID-19 disparities.
3. Move at the speed of **TRUST!**
4. Work with **trusted voices** and **trusted messengers** at the national and local levels.
5. **Exhibit agile leadership** and build innovative and strategic **public-private partnerships**

COVID19COMMUNITY.NIH.GOV

Community Engagement Alliance (CEAL)

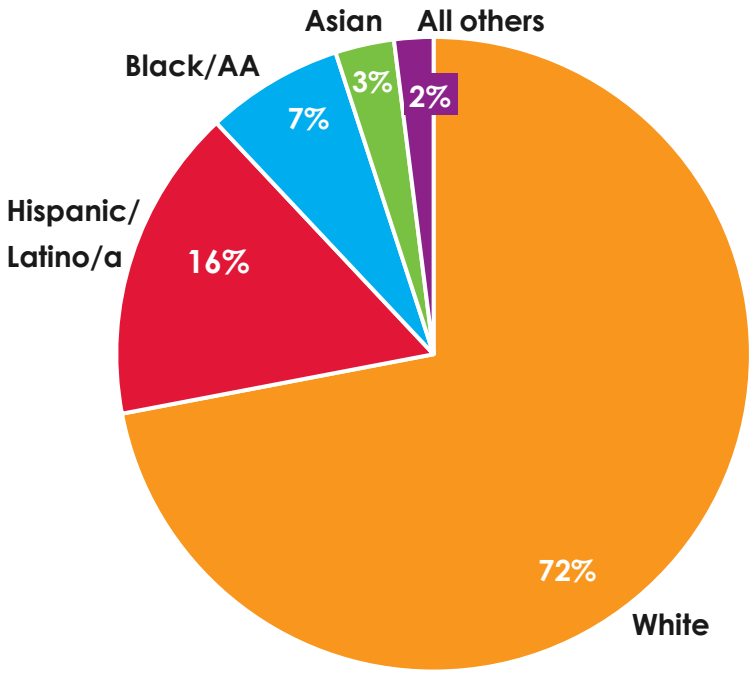
Outreach, engagement and inclusive participation efforts in communities disproportionately affected by the COVID-19 pandemic

- Establishing partnerships within communities hardest hit by COVID-19
- Addressing misinformation and mistrust through the voices of trusted leaders and messengers
- Fostering an understanding of trust in science and trust in research
- Accelerating inclusive participation in research and the uptake of beneficial treatments proven effective

An Ecosystem Fostering Inclusive Participation in COVID-19 Vaccine Trials

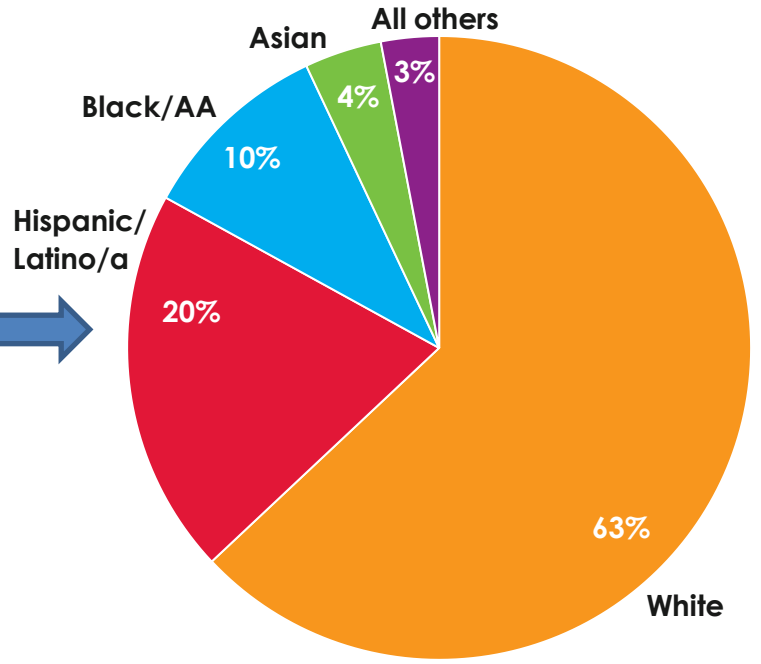
Moderna COVE Vaccine Study

COVE Study: Enrollment mid-September



- Trusted Partnerships
- Tailored messages
- Community Champions
- Adaptive platforms (Public-Private)

COVE Study: Enrollment late-October



https://twitter.com/moderna_tx/status/1306605434346917888/photo/1

https://www.modernatx.com/sites/default/files/content_documents/2020-COVE-Study-Enrollment-Completion-10.22.20.pdf

Rapid Acceleration of Diagnostics (RADx)

RADx Projects

RADx Tech

Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19

RADx Underserved Populations (RADx-UP)

Interlinked community-engaged demonstration projects focused on implementation strategies to enable and enhance testing of COVID-19 in vulnerable populations

RADx Radical (RADx-Rad)

Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing

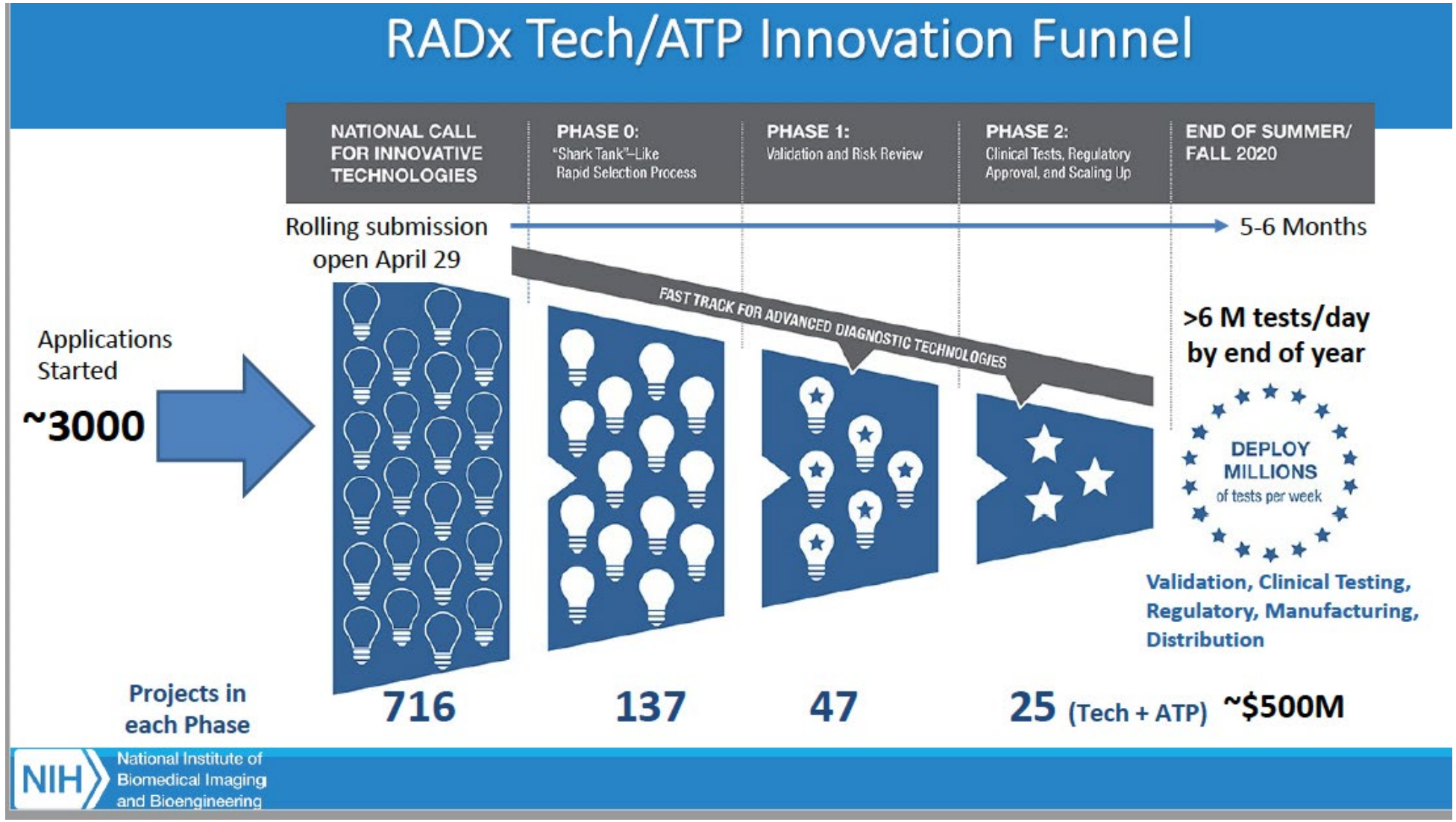
RADx Advanced Testing Program (RADx-ATP)

Rapid scale-up of advanced technologies to increase rapidity and enhance and validate throughput — create ultra-high throughput laboratories and “mega labs”

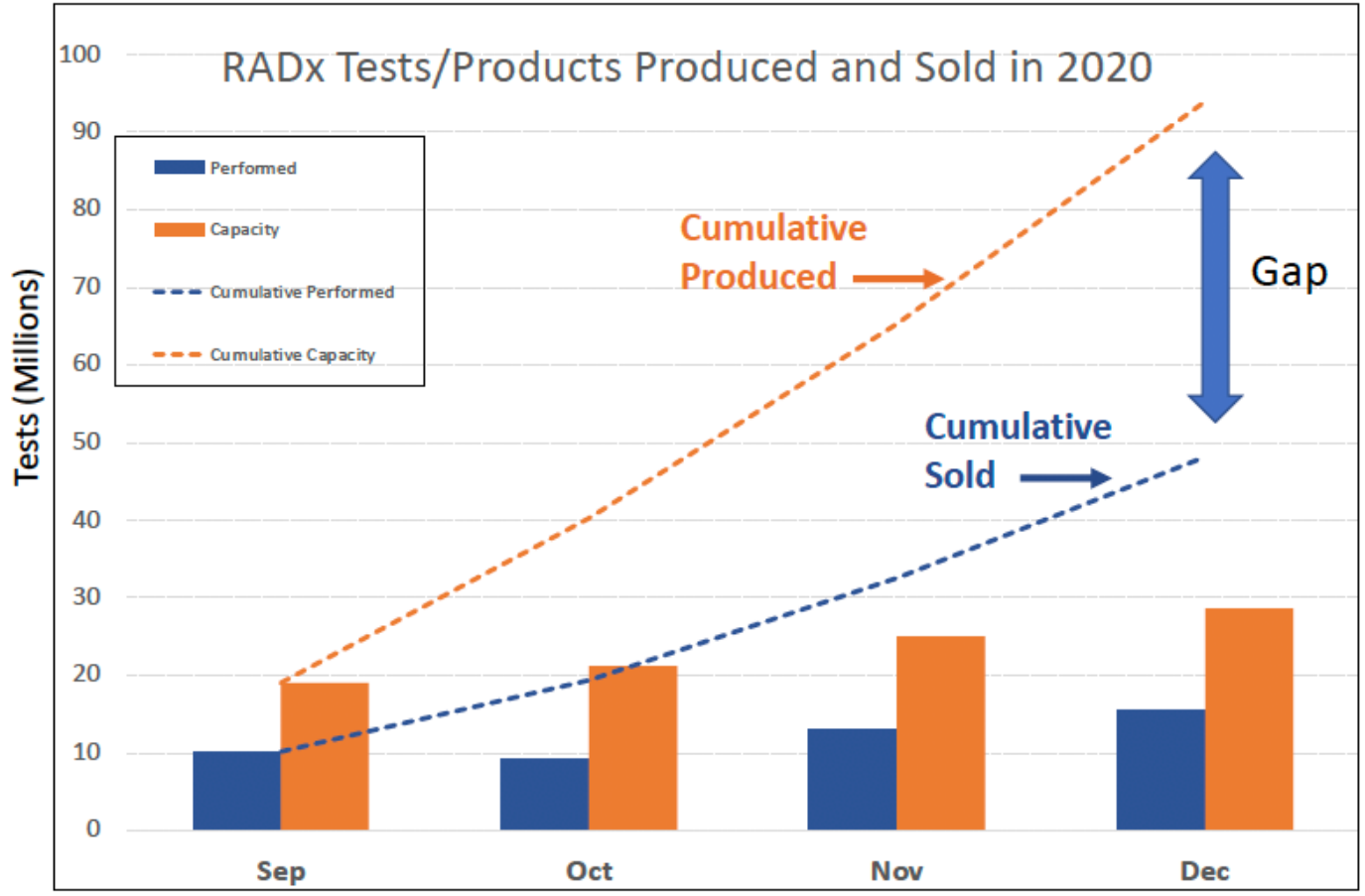
Data Management Support

Build an infrastructure for and support coordination of the various data management needs of many of the COVID-19 efforts

RADx Tech/ATP Innovation Funnel



RADx Impact in 2020



- **~94 million capacity in 2020**
- **~48 million sold in 2020**
- ~950k tests/day produced Dec 2020; ~550k/day sold
- ~14 EUAs and 1st OTC EUA
- ~150 Companies supported
- **Feb 2021**: Project millions OTC LFA tests/day
- **March 2021:** Project >2.5M tests/day

NIH National Institute of Biomedical Imaging and Bioengineering

RADx-Underserved Populations (RADx-UP)

RADx-UP

Overarching Goal

Enhance COVID-19 testing among underserved and vulnerable populations

Mechanism

Develop/create a **consortium of community-engaged research projects** designed to rapidly implement testing interventions

Strengthen the available data on disparities in infection rates, disease progression and outcomes, and **identify strategies to reduce these disparities** in COVID-19 diagnostics

September – November 2020

Phase I

- **Build infrastructure**
- **Rapidly implement testing, other capabilities**

Early 2021 – Summer/Fall 2021

Phase II

- **Integrate new advances**
- **Expand studies/ populations**

RADx-UP Strategies

- **Expand capacity to test broadly** for SARS-CoV-2 in highly affected populations, including asymptomatic persons.
- **Deploy validated point of care tests** as available, including self-test and saliva-based methods.
- **Inform implementation of mitigation strategies** based on isolation and contact tracing to limit community transmission.
- **Understand factors** that contribute to COVID-19 disparities and **implement interventions** to reduce these disparities.
- **Establish infrastructure** that could facilitate evaluation and distribution of vaccines and therapeutics.

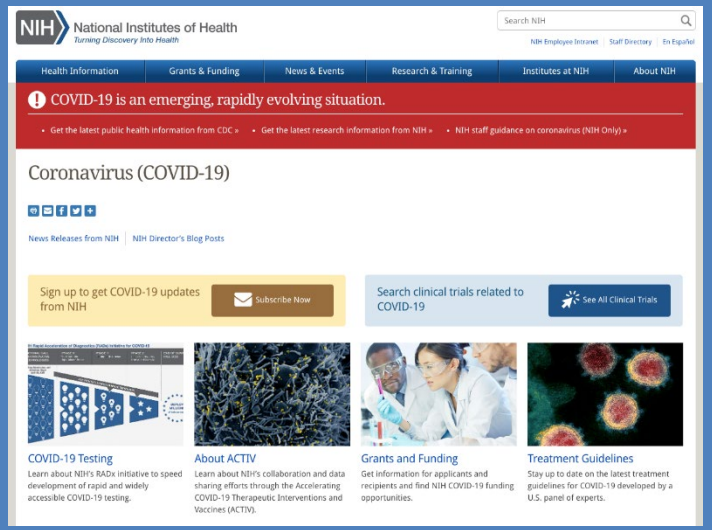
Communications

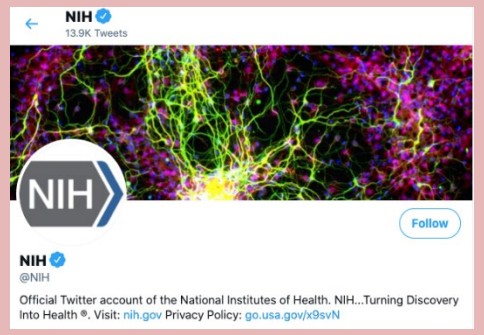
HHS CombatCOVID is a new HHS website to help communicate with and engage the public https://combatcovid.hhs.gov

NIH COVID-19 website provides the latest guidance and information available from CDC and NIH https://www.nih.gov/coronavirus

NIH Director's Blog offers updates and thoughts directly from Dr. Collins https://directorsblog.nih.gov/

News releases provide updates on recent publications, findings, funding opportunities, and more https://www.nih.gov/coronavirus-covid-19-news-releases





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Follow NIH on **social media**

Promoting Diversity, Equity, and Inclusion in Biomedical Research

Impetus to Addressing Challenges in 2020 and Beyond

- **Ongoing reality of inequities in biomedical research and the responsibility of all of us to address this**
- **Shared commitment to making changes**
- **A series of intense ICD meeting discussions in 2020**

Candid Input From Internal NIH Groups
(Early September 2020)

- **NIH Black/African American Senior Investigators**
  - *Proposed >10 solutions largely devoted to intramural recruitment*
  - *Retention and inclusion/safety*

- **8 Changes for Racial Equity (8CRE, pronounced "Acre")**
  - *Proposed 8 changes addressing diversity, equity and inclusion for NIH intramural and extramural workforce*

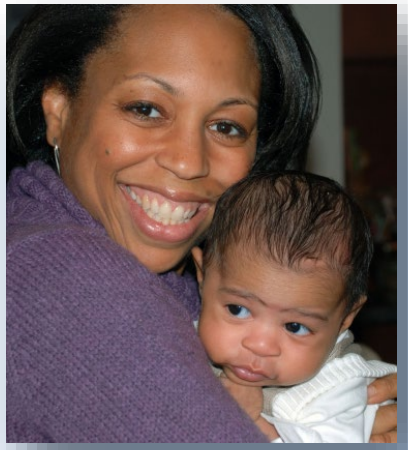
- **Anti-Harassment Steering Committee**
  - *Provided insight on racial equity efforts in the context of the 2019 NIH anti-sexual harassment campaign*

Approach

Create trans-NIH committees that report to the NIH Steering Committee and to the NIH Advisory Committee to the Director (ACD)

5 interrelated, but distinct, workstreams:

- Understanding stakeholder experiences through listening and learning
- New research on health disparities/inequities
- Internal workforce
- Extramural research workforce
- Talking and communicating with our internal external stakeholders




NIH...

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Turning Discovery Into Health