

NIH Director's Report

*Council of Councils
September 8, 2022*



Lawrence A. Tabak, DDS, PhD
Performing the Duties of the Director of NIH
Department of Health and Human Services



Topics for Today

- NIH Leadership Changes
- NIH Budget Update
- COVID and Monkeypox Updates
- NIH Public Access Policy
- Initiative Updates: RECOVER, N3C, STRIVE



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Retirement:
**Director, Division of Program Coordination,
Planning, and Strategic Initiatives**



James M. Anderson, MD, PhD

Appointment:
Acting Director, Division of Program
Coordination, Planning, and Strategic Initiatives



Bob Eisinger, PhD

**Retirement:
Director, National Cancer Institute**



Norman E. "Ned" Sharpless, MD

**Appointment:
Director Designee, National Cancer Institute (NCI)**



Monica Bertagnolli, MD

Retirement:
**Director, National Institute of Allergy and
Infectious Diseases**



Anthony S. Fauci, MD

**Appointment:
Acting Deputy Director for Intramural Research**



Nina Schor, MD, PhD

Appointment:
Director of the Office of Equity, Diversity, and Inclusion



Kevin Williams, JD

**Appointment:
Acting Deputy Director, Advanced Research
Projects Agency for Health (ARPA-H)**



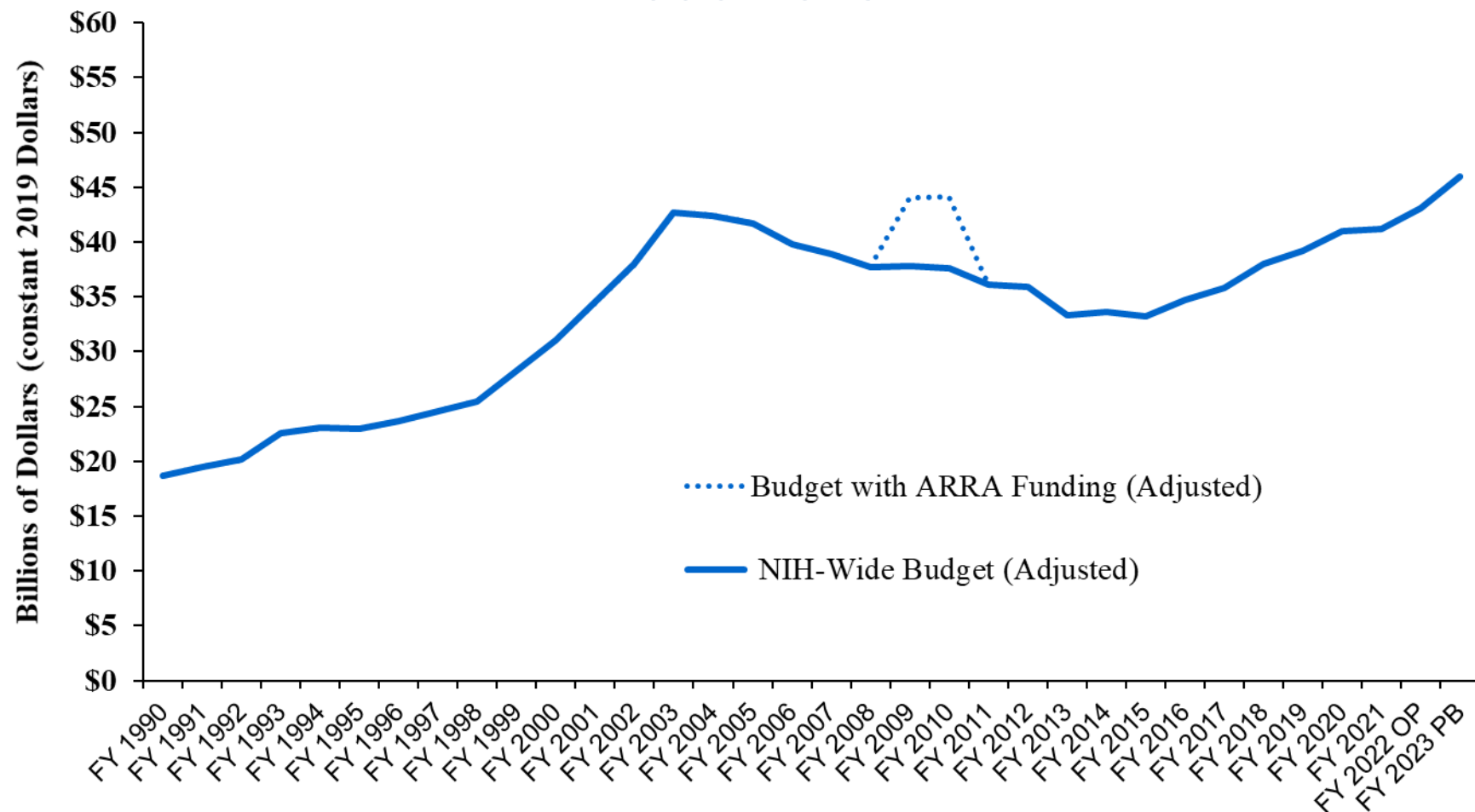
Adam Russell, DPhil

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National Institutes of Health Funding 1990-2023



Notes: Dollar values are adjusted to 2019 dollars using the Biomedical Research and Development Price Index (BRDPI), <http://officeofbudget.od.nih.gov/gbiPriceIndexes.html>. Includes \$1 billion for ARPA-H in FY 2022 and a \$5 billion request in the FY 2023 President's Budget. Does not include the President's Budget request of \$12.1 billion in mandatory resources to support pandemic preparedness. Sources: the NIH's Office of Extramural Research and the Office of Budget (March 2022).

FY 2022 NIH Appropriations

	FY 2021	FY 2022	Change from FY 2021 (\$)	Change from FY 2021 (%)
NIH Program Level	\$42.94B	\$45.18B	+\$2.24B	+5.2%

- \$2.24 billion increase, or 5.2 percent, over FY 2021
- General increase for Institutes/Centers of 3.4 percent
- Specific increases include:
 - ARPA-H (\$1 billion)
 - Alzheimer's disease (\$289 million)
 - Cancer research (\$150 million)
 - Opioids research (\$75 million)
 - BRAIN Initiative (\$60 million)
 - Health disparities (\$50 million)

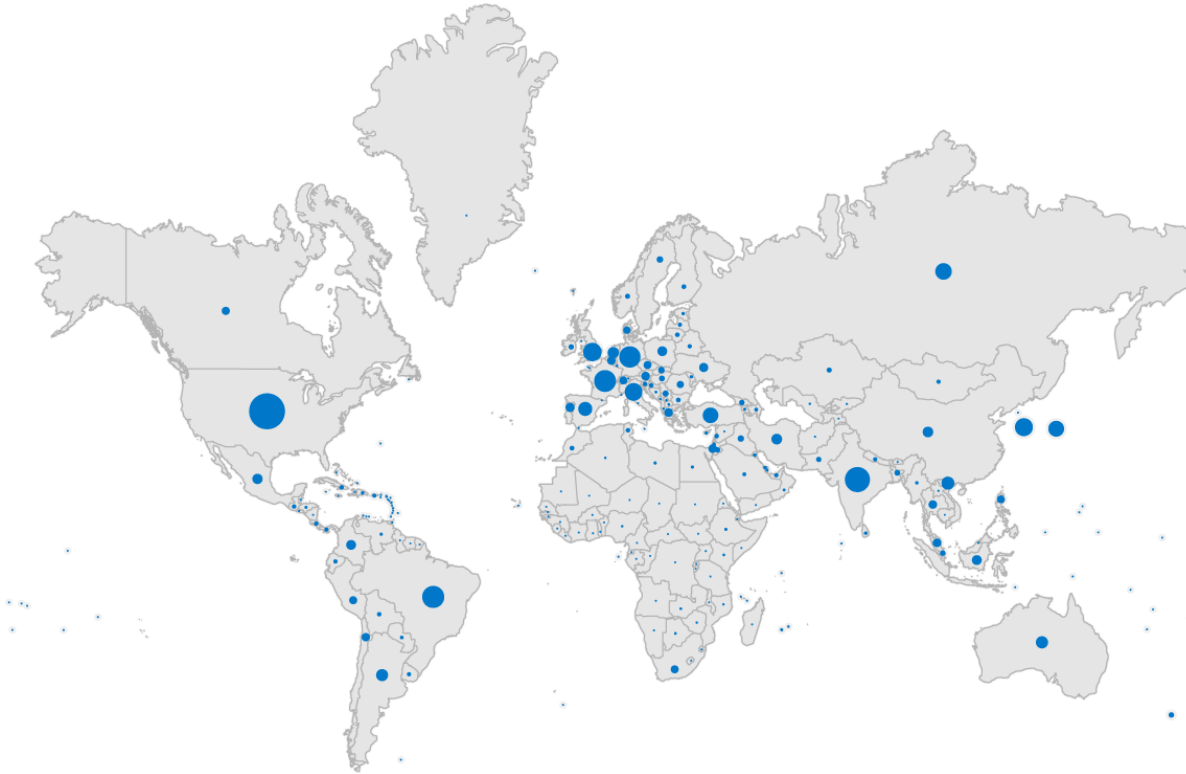
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COVID-19 Pandemic

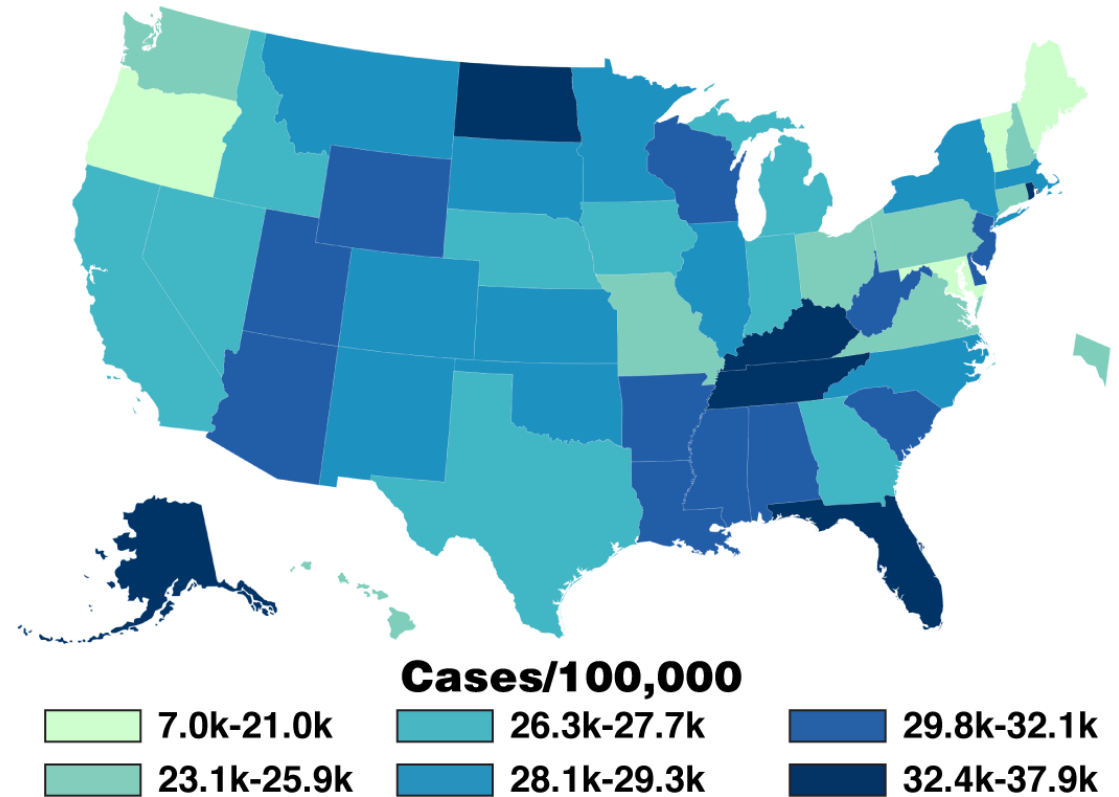
Globally



Reported cases: 593.3 million
Reported deaths: 6,446,547

Sources: WHO; KFF. Data as of 8/22/2022.

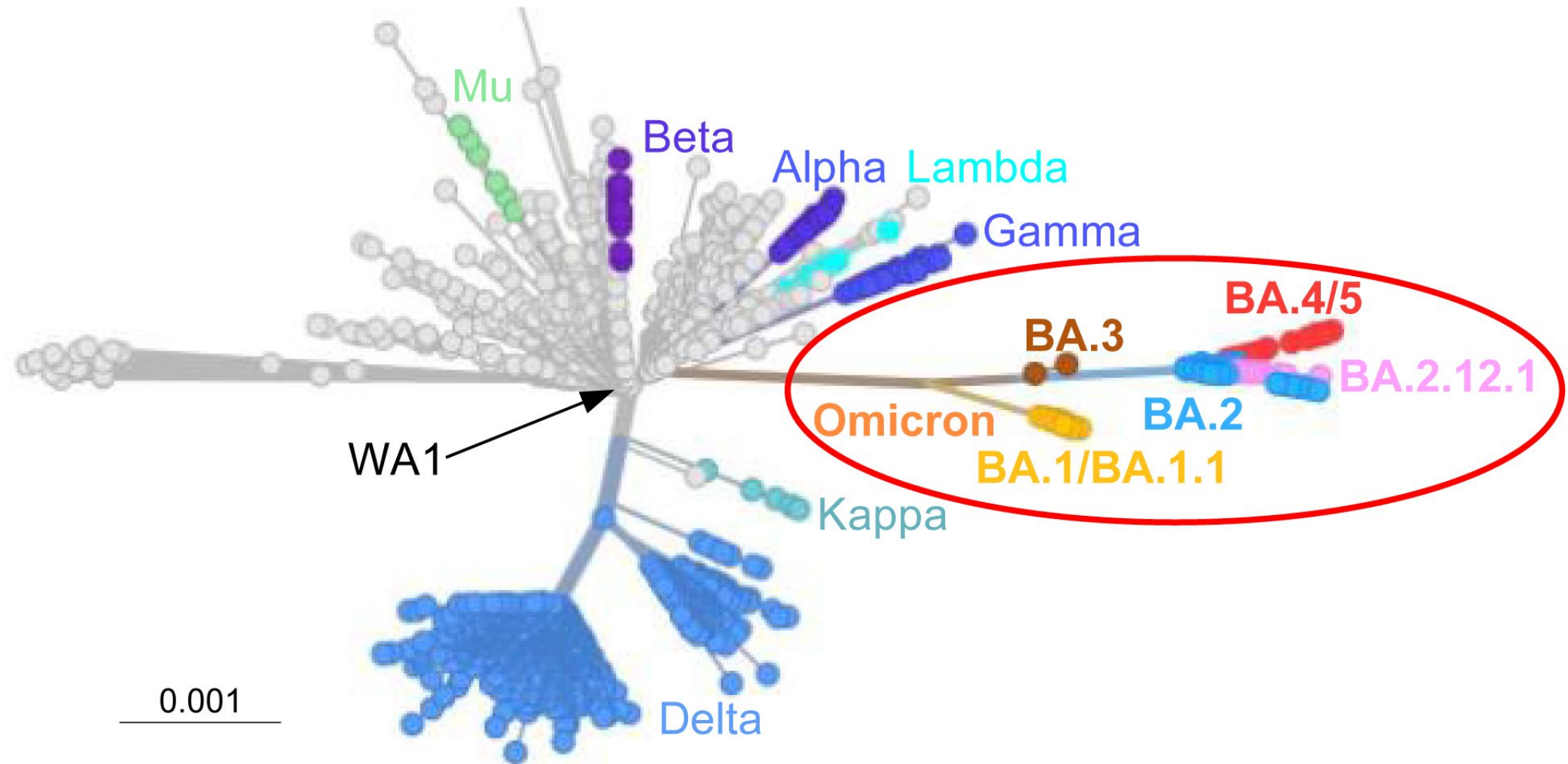
United States






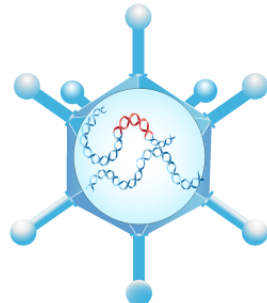


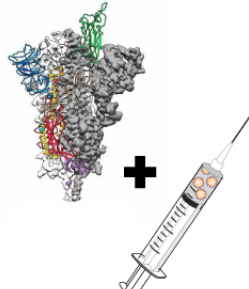


Reported cases: 93.2 million
Reported deaths: 1,034,668

Source: CDC. Data as of 8/22/2022.

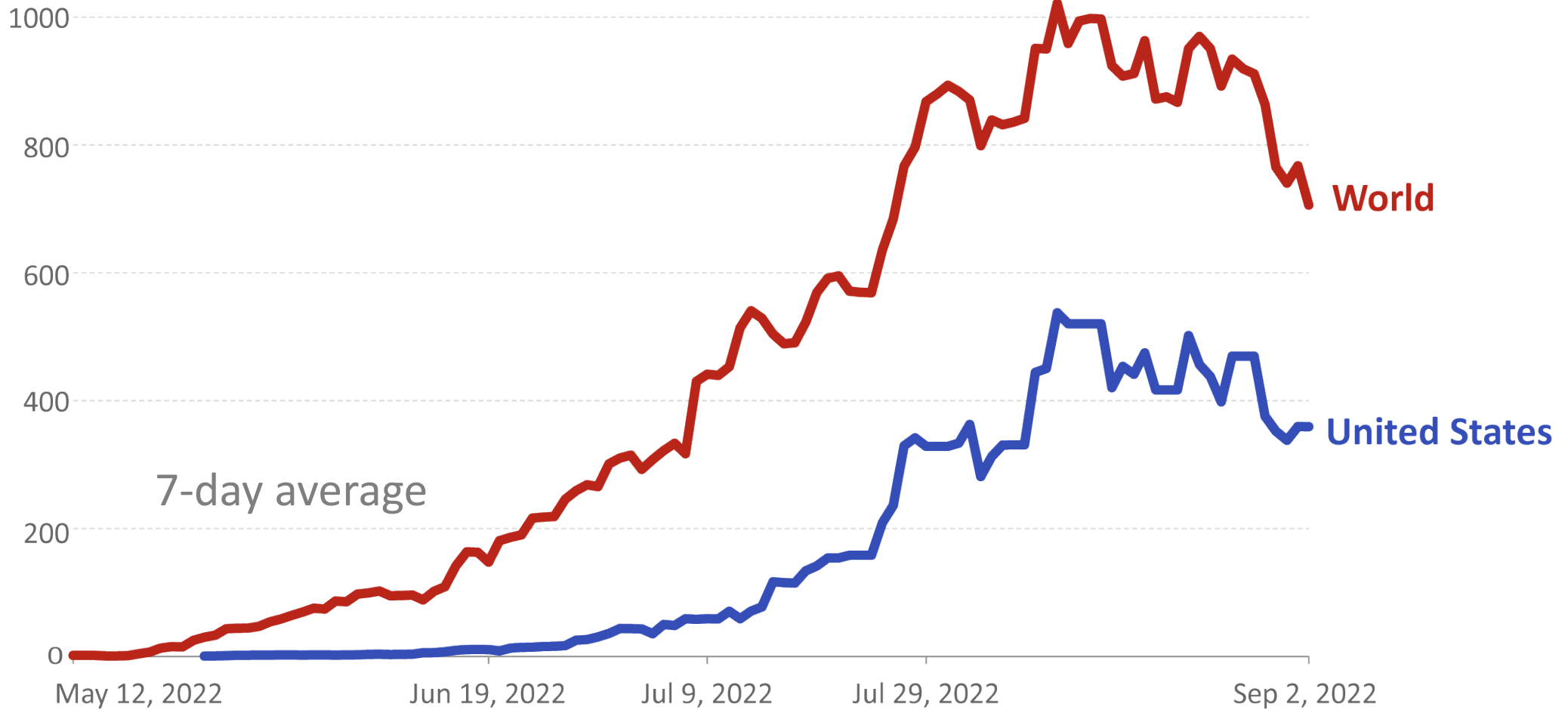
SARS-CoV-2 “Family Tree”



COVID-19 Vaccines in US Government Development

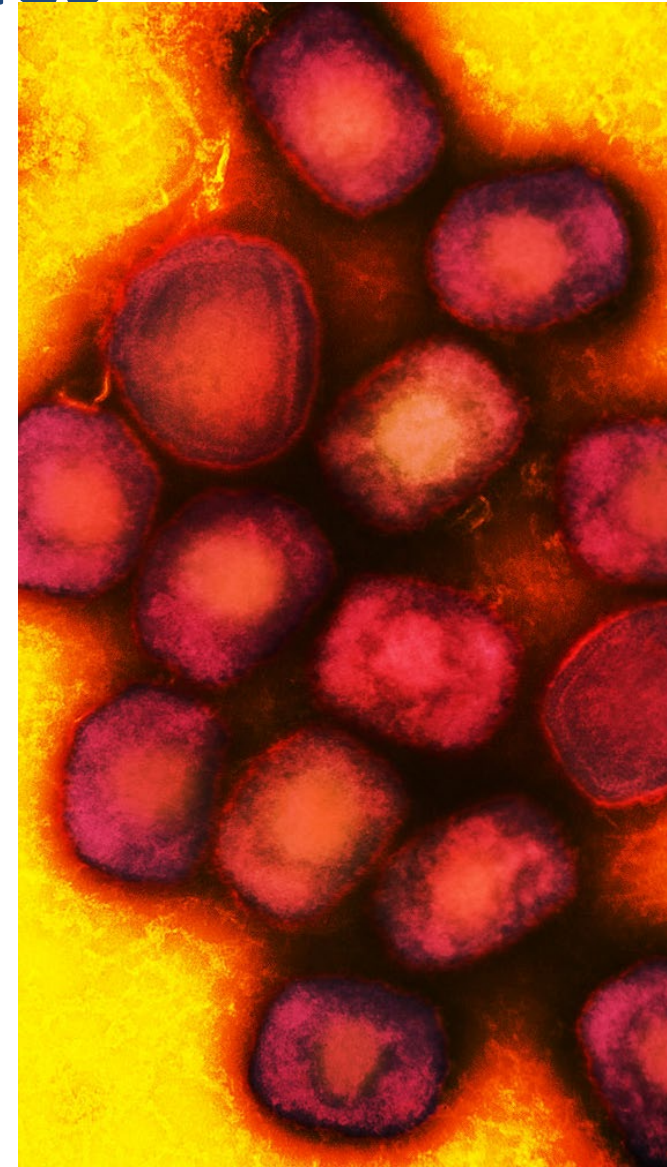
Platform	Immunogen		Developer	Status
Nucleic Acid (mRNA)	S2P			■ BLA (Age 18+); EUA (Age 6 mo-17)
	S2P			■ BLA (Age 16+); EUA (Age 6 mo-15)
Adenovirus Vector	S2P			■ EUA (Age 18+)
	Wild-type spike			■ EUA/BLA TBD
Recombinant Protein and Adjuvant	S2P			■ EUA request 2/2022
	S2P			■ EUA (Age 12+)

Monkeypox Daily Cases



Planned NIAID Clinical Trials Monkeypox Treatments & Vaccines

- **Sept. 2022:** U.S. clinical trial of **tecovirimat (TPOXX)**
- **Sept. 2022:** Clinical trial of **tecovirimat (TPOXX)** in the Democratic Republic of the Congo
- **Fall 2022:** Intradermal administration of a low-dose JYNNEOS monkeypox vaccine



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Public Access to Federally Funded Research Results

2013 – Expanding Access

- Federal departments/agencies with >\$100M in R&D expenditures
- Develop and implement public access plans and policies
 - **12-month embargo** for scholarly publications
 - Plans for maximizing access to scientific data

2022 – Increasing Equitable Access

- All Federal departments/agencies
- Develop new or update existing public access plans and policies
 - **No embargo** for scholarly publications
 - Scientific data **made accessible at publication**
 - Require digital Persistent Identifiers (PIDs) and metadata for research outputs

Next Steps

- **Public access plans due to OSTP & OMB no later than 180 days (~February)**
 - Agency public access policies: Developed by December 31, 2024; Implemented by December 31, 2025
 - PIDs Requirement/Metadata: Developed by December 31, 2026; Implemented date by December 31, 2027
- **Immediate next steps for NIH – Plan Development**
 - Revisions to NIH Public Access Policy
 - NIH DMS Policy already underway after extensive consultation; to be implemented January 25, 2023
 - Will undertake outreach to stakeholders and interagency in development

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NIH Researching COVID to Enhance Recovery (RECOVER) Initiative

Goal: Rapidly improve our understanding of and ability to predict, treat, and prevent Post-Acute Sequelae of SARS-CoV-2 Infection (PASC)



RECOVER Key Scientific Aims

- Understand clinical spectrum and biology underlying COVID-19 recovery over time
- Define risk factors, incidence/prevalence, and distinct PASC sub-phenotypes
- Study pathogenesis over time and possible relation to other organ dysfunction and disorders
- Identify interventions to treat and prevent PASC

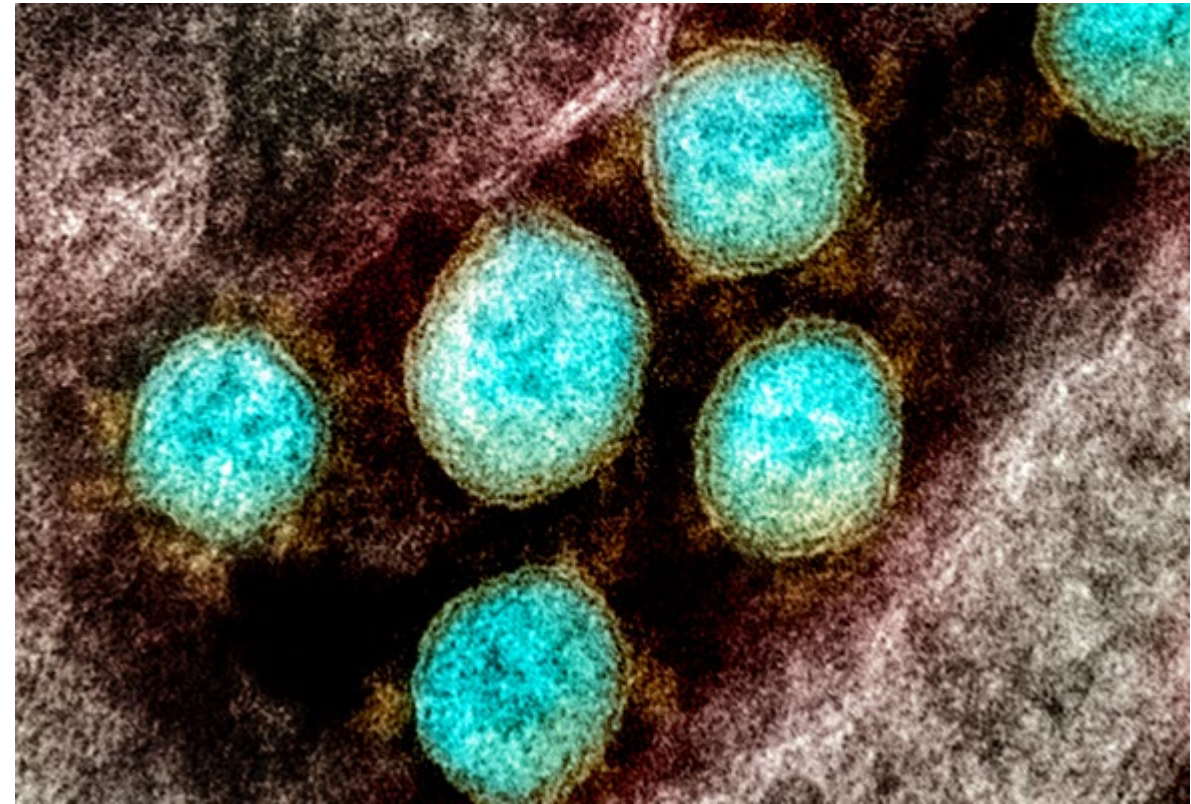
RECOVER Guiding Principles

- Patient-centered
- National scale, inclusive and diverse, patient participation
- Standardized procedures
- Adaptive



National COVID Cohort Collaborative (N3C)

- Collaborators contribute and use electronic health record data (EHR) to study clinical course of COVID-19
- Diverse, deidentified data from
 - 75 sites in 49 states
 - 15.2 million people
 - 6.0 million COVID cases
 - 1.6 billion clinical observations



Partners & Collaborators:

NCATS * NIGMS * CTSAs * IDeA-CTRs * NLM * ODSS * NIAID * NIBIB * NICHD * NHLBI * THRO * FDA * BARDA * CMS * ONC , CD2H, Palantir * Datavant * Acumen * SAMVIT * OCHIN * Regenstreif * MDClone * Microsoft * Sage Bionetworks

N3C Controlled Access Database

Answering Urgent Public Health Questions



- Data are secure and cannot be removed
- Extensive learning, training, and community resources available
- >70 preprints or publications, >1000 Google citations
 - Defining PASC and risk factors for PASC
 - Effectiveness of monoclonal antibody treatment
 - Unpublished: Paxlovid rebound

STRIVE: Strategies and Treatments for Respiratory Infections and Viral Emergencies

- New component of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership
- Purpose
 - Identify better treatments for severe respiratory infections
 - Maintain clinical trials infrastructure for pandemic preparedness
- Global footprint
- Scope
 - COVID-19 – initial focus
 - Potential to study additional pathogens in the future



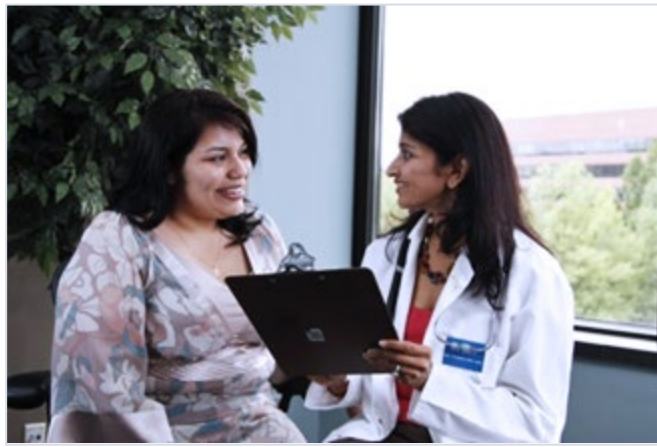
STRIVE: Potential Therapies to Investigate

- Antiviral agents
 - Small molecule antiviral drugs
 - Passive immunity agents
- Host response agents
 - Immunomodulators
 - Host pathways
- Strategies of combination therapy
- Repurposed drugs
- Novel drugs
- Supportive care approaches

Trial #1 - Protease Inhibitor

Anticipated Trial #2 -
Strategy trial evaluating use of
immunomodulatory agents





NIH...

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@NIHDirector/Twitter

Turning Discovery Into Health

