#### Director's Update Francis S. Collins, M.D., Ph.D. Director, National Institutes of Health Council of Councils September 11, 2020







## **Topics for Today**

- Changes in Leadership
- NIH Budget
- NIH and COVID-19
  - ACTIV
  - RADx
- Congress and the media

#### **Changes in Leadership: New Hires**

- Michael Chiang, MD Director, NEI (Late 2020)
- Lindsey Criswell, MD, MPH, DSc Director, NIAMS (Early 2021)
- Rena N. D'Souza, DDS, MS, PhD Director, NIDCR (Late 2020)
- Rick Woychik, PhD Director, NIEHS and National Toxicology Program (June 7, 2020)
- Shannon Zenk, PhD, MPH, RN, FAAN Director, NINR (Fall 2020)











#### **Changes in Leadership: Retirement**



Hannah A. Valantine, MD Chief Officer for Scientific Workforce Diversity

## **National Institutes of Health Funding**



#### **COVID-19 Emergency Supplemental Appropriations** (Dollars in Millions)



## January 3, 2020 Volume 367 Issue 6473

## Novel Human Virus? Pneumonia Cases Linked to Seafood Market in China Stir Concern

**By Dennis Normile** 

Convoluted shapes from simple rules pp. 24 & 91 The Washington Post

January 9, 2020

## China Identifies New Strain of Coronavirus as Source of Pneumonia Outbreak

**AS Fauci/NIAID** 

# Coronavirus Task Force Established January 29, 2020



#### President Visits NIH, Tours Vaccine Research Center March 3, 2020





## **Testing NIH Workforce for COVID-19** First Case on NIH Campus Reported March 15, 2020



Holly Ann Baus and Keith Kikora

Clinically trained NIH volunteers begin testing procedures to keep the Clinical Center safe



LTJG Ruth Widener and LCDR Brenda Holbrook

#### **NIH and COVID-19: Topics**

- ACTIV: Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
- Rapid Acceleration of Diagnostics (RADx) Initiative
- COVID-19 Serology: NCI



# Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

April 17: NIH announced the launch of a public-private partnership; dedicated to:



- Establishing a collaborative framework for prioritizing therapeutic candidates and accelerating vaccine evaluation
- Accelerating clinical trials of promising agents and leveraging existing clinical trial networks while maintaining rigorous safety standards
- Coordinating regulatory processes and leveraging assets among all partners

#### Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)



#### **ACTIV Public-Private Partnership**



#### **Therapeutics Prioritized for Testing in Clinical Trials**

- **ACTIV-1:** Immune Modulators (*planning to launch mid-late September*)
  - Phase 3 inpatient trial
- ACTIV-2: Monoclonal Antibodies and Other Therapies (launched August 3)
  - Phase 2/3 outpatient trial
- ACTIV-3: Monoclonal Antibodies and Other Therapies (launched August 4)
  - Phase 3 inpatient trial
- ACTIV-4: Antithrombotics (launched September 10)
  - Phase 3 pre-hospitalized/outpatient trial
  - Phase 3 hospitalized/inpatient trial
  - Phase 3 post-hospitalized/convalescent trial, projected to launch mid-September
- **ACTIV-5:** Other Promising Treatments (*planning to launch mid-September*)
  - Phase 2 inpatient trial

#### **Operation Warp Speed Rose Garden Press Briefing May 15, 2020**



#### **Selected COVID-19 Vaccine Candidates**

Platform	Developer	Phase 1/2	Phase 2/3
mRNA	moderna	Completed	Ongoing
	BIONTECH	Completed	Ongoing
Viral vector	OXFORD AstraZeneca	Completed	Ongoing
	Janssen J	Ongoing	
Protein subunit	gsk SANOFI 🎝	Ongoing	
	<b>NOVAVAX</b> Creating Tomorrow's Vaccines Today	Ongoing	

### **Rapid Acceleration of Diagnostics (RADx) for COVID-19**



#### RADx-tech

Competitive, three-phase challenge to identify best candidates for at-home or pointof-care tests



#### RADx Advanced Technology Platforms (RADx-ATP)

Rapid scale-up of advanced technologies to enhance and validate throughput – create ultra-high throughput machines and facilities



#### RADx Underserved Populations (RADx-UP)

Interlinked community-based demonstration projects focused on implementation strategies to enable and enhance testing in vulnerable populations



#### RADx Radical (RADx-rad)

Develop novel, non-traditional approaches/applications

#### **RADx-tech Initiative**

- Goal: Accelerate innovation in, development and commercialization of, and implementation of COVID-19 testing
- Approach:
  - Fund early innovative diagnostic technologies
  - Advance late-stage diagnostic technologies to expand testing infrastructure
  - Identify effective testing implementation strategies in underserved populations
  - Work closely with other government agencies (FDA, BARDA, CDC)

#### NIH Rapid Acceleration of Diagnostics (RADx) Initiative for COVID-19



#### **RADx Phase 2 Awards**



#### **Point-of-care tests**

MatMaCorp Lincoln, NE	<b>Maxim Biomedical Inc</b> Rockville, MD	<b>Mesa Biotech</b> San Diego, CA	<b>MicroGEM International</b> Charlottesville, VA
<b>Quidel</b> San Diego, CA	<b>Talis Biomedical</b> Menlo Park, CA		
Lab-based tests			
<b>Aegis Sciences</b> Nashville, TN	<b>Broad Institute</b> Cambridge, MA	<b>Ceres Nanoscience Inc</b> Manassas, VA	<b>Fluidigm</b> San Francisco, CA
<b>Ginkgo Bioworks</b> Boston, MA	<b>Helix OpCo</b> San Mateo, CA	<b>Illumina</b> San Diego, CA	Mammoth Biosciences, Inc South San Francisco, CA
<b>PathGroup</b> Nashville, TN	<b>Sonic Healthcare USA</b> Austin, TX		
www.nit	More deta bib.nih.gov/covid-19/radx-t	ails available at: ech-program/radx-tech-pha	ise2-awards

#### COVID-19 Serology: NCI Involvement

- NCI runs serology lab at Frederick National Lab for HPV research
- Pivoted HPV lab to COVID lab mid-March
  - Acquired samples, reagents
  - Developed assays
  - Cross-compare with academia, NIAID, and CDC
- Approached by FDA for performance testing
  - Important change in regulatory environment for serology tests
- Congressional Appropriation (4/24)





34 STAT. 63	PUBLIC LAW 116-139-APR. 24, 2020		
	Public Law 116–139 116th Congress An Act		
Apr. 24, 2020 [H.R. 266]	Making appropriations for the Department of the Interior, environment, and related agencies for the fiscal year ending September 30, 2019, and for other purposes.		
Paycheck Protection Program and Health Care Enhancement Act.	Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, SECTION 1. SHORT TITLE.		
	This Act may be cited as the "Paycheck Protection Program and Health Care Enhancement Act".		
15 USC 9001	SEC. 2. TABLE OF CONTENTS.		
lote.	The table of contents for this Act is as follows:		
	Sec. 1. Short title. Sec. 2. Table of contents. Sec. 3. References.		

#### Senate HELP Committee Hearing Shark Tank: New Tests for COVID-19, May 7, 2020



#### Senate HELP Committee Hearing Vaccines: Saving Lives, Ensuring Confidence, and Protecting Public Health, September 9, 2020



#### **COVID-19 Communications**



## **COVID-19 Communications**





# **NIH**... *Turning Discovery Into Health www.nih.gov/hope* directorsblog.nih.gov







