COVID-19 Research Initiatives at the FNL

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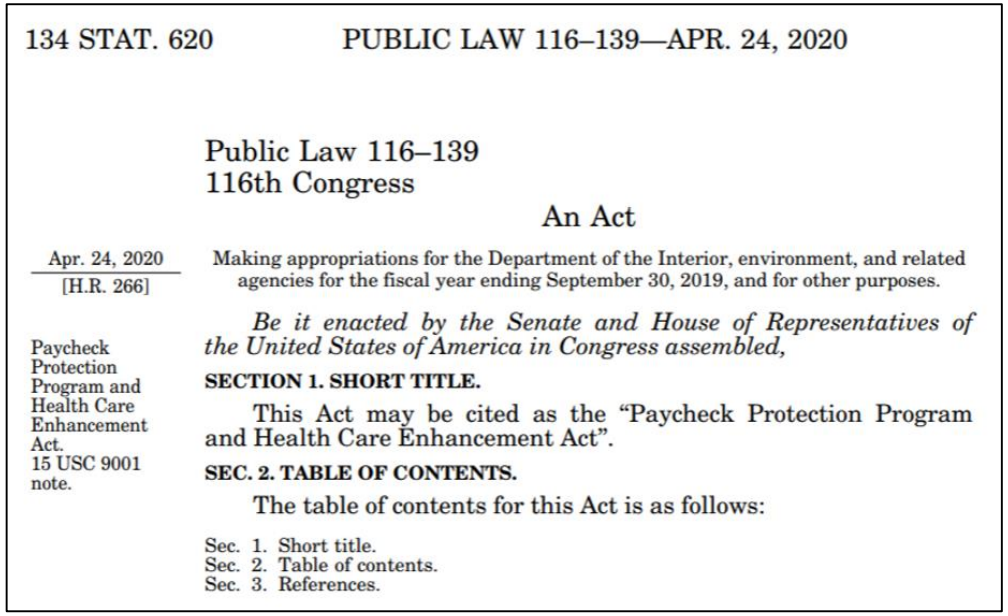
Topics for today

- Serology at Frederick National Lab
- Serology network
- Serology dashboard
- COVID-19 natural history in cancer patients
- Cancer prevention & screening

Supplemental funding from Congress

- Enacted April 24th
- $306M for NCI to **develop, validate, improve, and implement serological testing and associated technologies**
- COVID-19-focused and ***distinct from annual appropriation***



134 STAT. 620 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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Paycheck Protection Program and Health Care Enhancement Act.
15 USC 9001 note.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Paycheck Protection Program and Health Care Enhancement Act".

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

Sec. 1. Short title.
Sec. 2. Table of contents.
Sec. 3. References.

Convert part of HPV serology lab to SARS-CoV-2 serology

A collaborative research effort with several groups: NIAID, FDA, CDC, Mount Sinai, others

Shorter term goals

1. Characterize performance of different serologic assays, correlate with neutralization assays, understand possible cross-reacting sera from prior to epidemic;
2. correlations with serologic tests submitted to FDA

Longer term goals

Understand implications of being seropositive (e.g., resistance to reinfection), duration of seropositivity

Cohort oriented research projects: COVID-19 longitudinal trial of cancer patients, others

Summary of initial 70 commercial serology devices evaluated by FNLCR serology laboratory

- Focus on IgG antibody tests; IgM becomes positive at about the same time as IgG and decreases faster than IgG
- **Sensitivity** (detect true positives): Varies from 30% to 100%
- **Specificity** (does not detect false-positives): Varies from 87% to 100%
- Results sent to FDA to help FDA determine suitability for Emergency Use Authorization (EUA)
- FDA web site with data for EUA tests: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance

Additional activities at FNL serology lab

- FNL protein expression lab is producing large amounts of SARS-CoV-2 antigens for use in serologic assays, at FNL and NIBIB
- Serology lab is developing quantitative SARS-CoV-2 antibody assays
  - Until now, assay results have been qualitative
- Serology lab is developing a “standard” pooled serum for US govt and beyond; collaboration with NIAID, CDC, BARDA
  - Will eventually be linked to WHO standard serum when it is available

Some SARS-CoV-2 serology questions

- **It is not currently known**:
  - whether being antibody-positive is associated with protection against reinfection
  - what antibody levels may be associated with protection
  - how long protection will last
- NCI is co-funding extramural research with NIAID and CDC to address these questions
- For candidate SARS-CoV-2 vaccines, **will induction of neutralizing antibodies confer protection?**
  - The serological standard will enable direct comparisons of immunogenicity between candidate vaccines

Extramural Serological Sciences Network

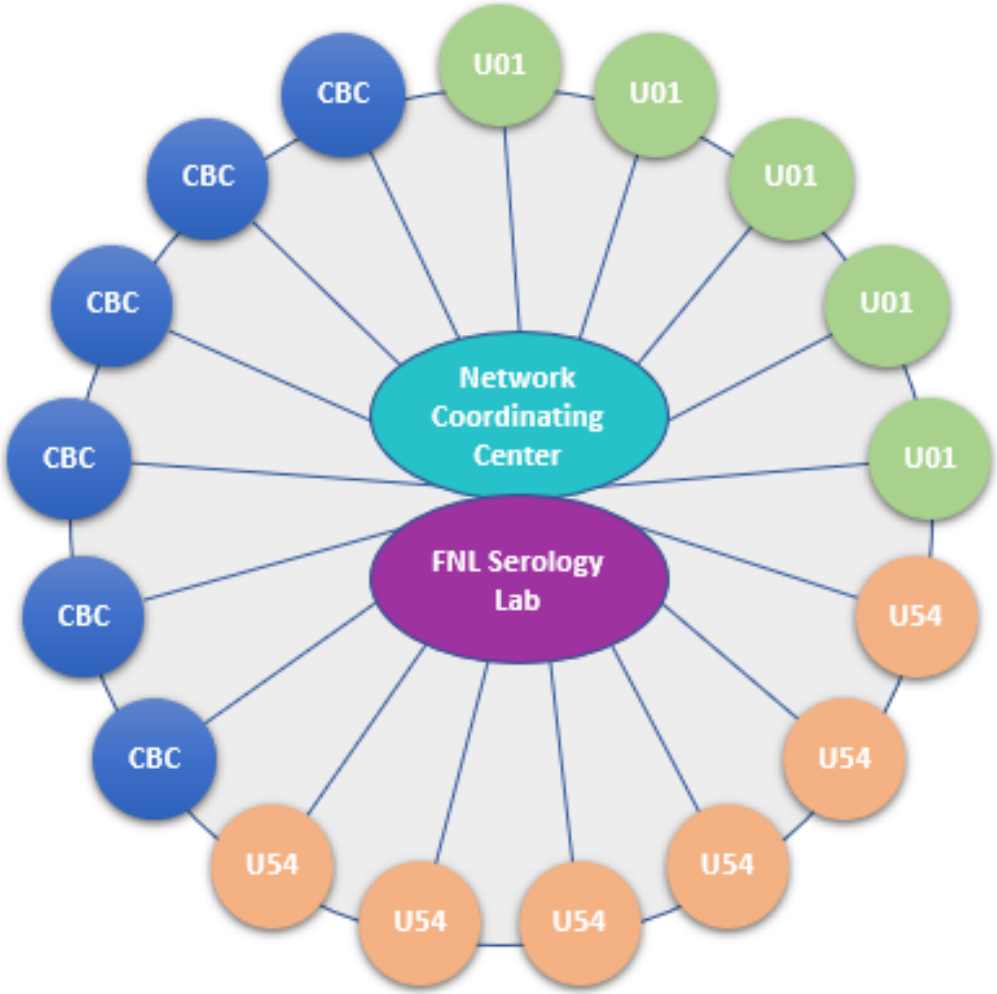
Serological Sciences Network for COVID-19 (SeroNet)

GOALS

To rapidly expand understanding of all aspects of the immune response associated with SARS-CoV-2 viral infection.

- Increase national capacity for high-quality serological testing
- Develop serological assays for deployment to test for SARS-CoV-2 induced immune responses
- Understand the mechanisms driving the serological, humoral and **cellular immune responses**
- Determine the serological correlates of disease pathogenesis and protection against future infection

SeroNet “hub and spokes”



4-8 CBCs: Serological Sciences Capacity Building Centers (RFP)

4-8 U54s: Serological Sciences Centers of Excellence (RFA)

5-10 U01s: Serological sciences projects (RFA)

Serological Sciences Network for COVID-19 (SeroNet)

Capacity Building Centers (Contracts)

- Develop and expand serological testing capacity
- 4-8 contracts with academic and/or private sector through FNLCR

Serological Sciences Centers of Excellence (U54)

Each Center:

- 2-3 Research Projects
- Administrative Core
- Optional shared resource core
- 4-8 awards

Serological Sciences Research Projects (U01)

- Up to $500K direct costs per year, up to 5 years
- 5-10 awards

Network Coordinating Center

FNL Serology Lab

Tracking SARS-CoV-2 seroprevalence and more

Developing a SARS-CoV-2 serology data warehouse and dashboard

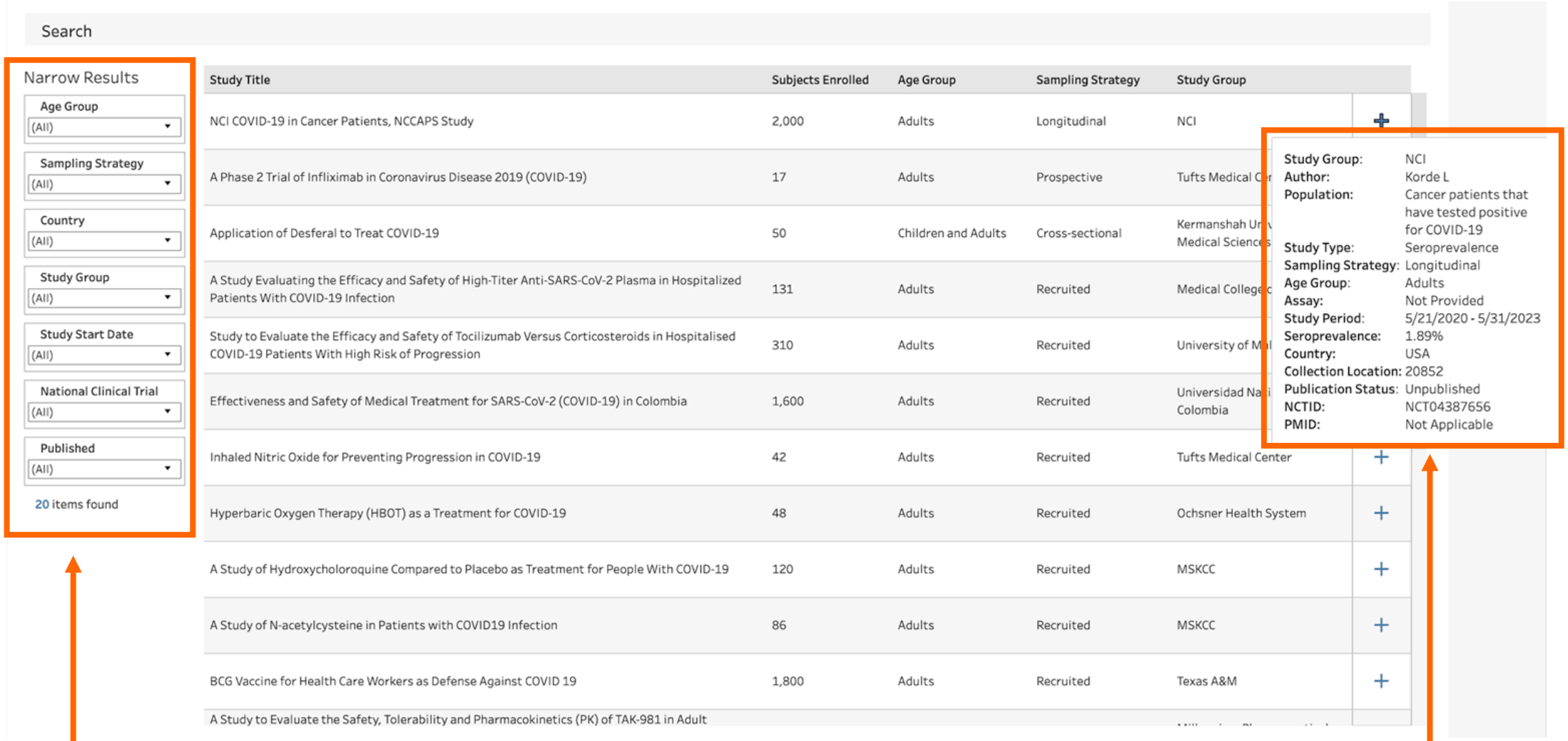
- Early June: HHS, CDC, NIAID ask NCI to develop data warehouse & dashboard for tracking SARS-CoV-2 seroprevalence and other US-based serology studies
- Builds on FNL dashboard expertise developed with NCI Clinical Trials Reporting Program (CTRP), other databases
  - Collaboration between NIAID, CDC, NCI
- Key features:
  - A publicly accessible data warehouse to systematically document and track SARS-Cov-2 serology studies and associated test results
  - A tracking dashboard to visualize SARS-Cov-2 serology data and present results overall and by key strata

Vision for Sero-tracker

Infrastructure to hold information and allow user access to dashboard and reports

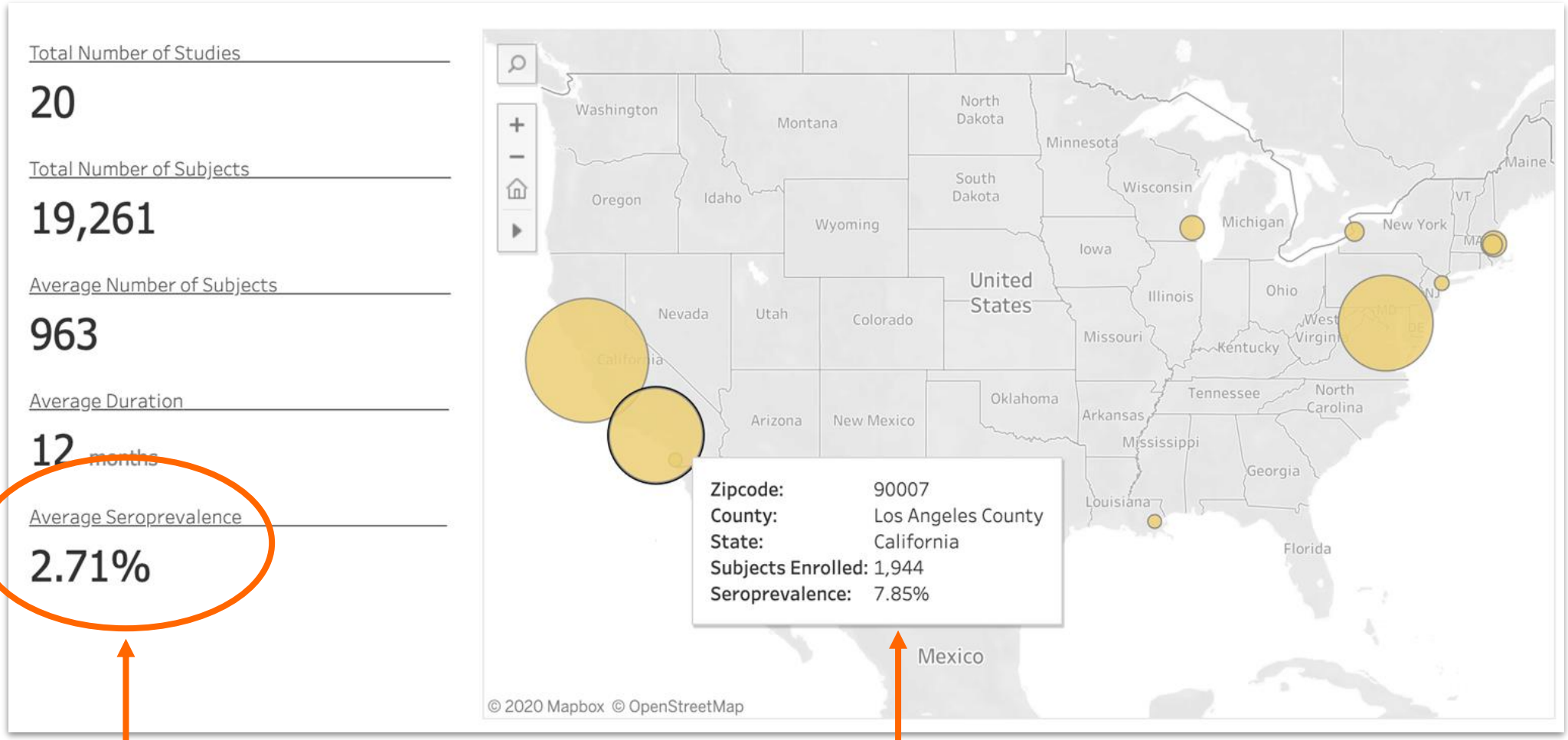
- Comprehensive view of near real-time COVID-19 status
- Identification of gaps and disparities across demographic factors
- Scientific assessment of study results
- Transparency of government funding

Project Identifier	National_Clinical_Trial_Identifier
Study name	Study reference
Study_Design	Comments
Study population	Zip Code
Study_Keywords	Test specificity
Sampling strategy	Collection Date
Collection Country	Gender
Collection_State	Study Title
Number_of_Participants	Study Description
Collection_Period	Study Date
Subject_Age_Group	Test Manufacturer
Name and type of test	Assay Metadata
Test sensitivity	Tested prevalence (Seroprevalence)



Sortable

Dynamic Popups showing any data elements deemed appropriate.



Clear highlight of seroprevalence

Dynamic popups showing any data elements deemed appropriate.

Longitudinal natural history of COVID-19 in people with cancer

NCI COVID-19 in Cancer Patients Study (NCCAPS)

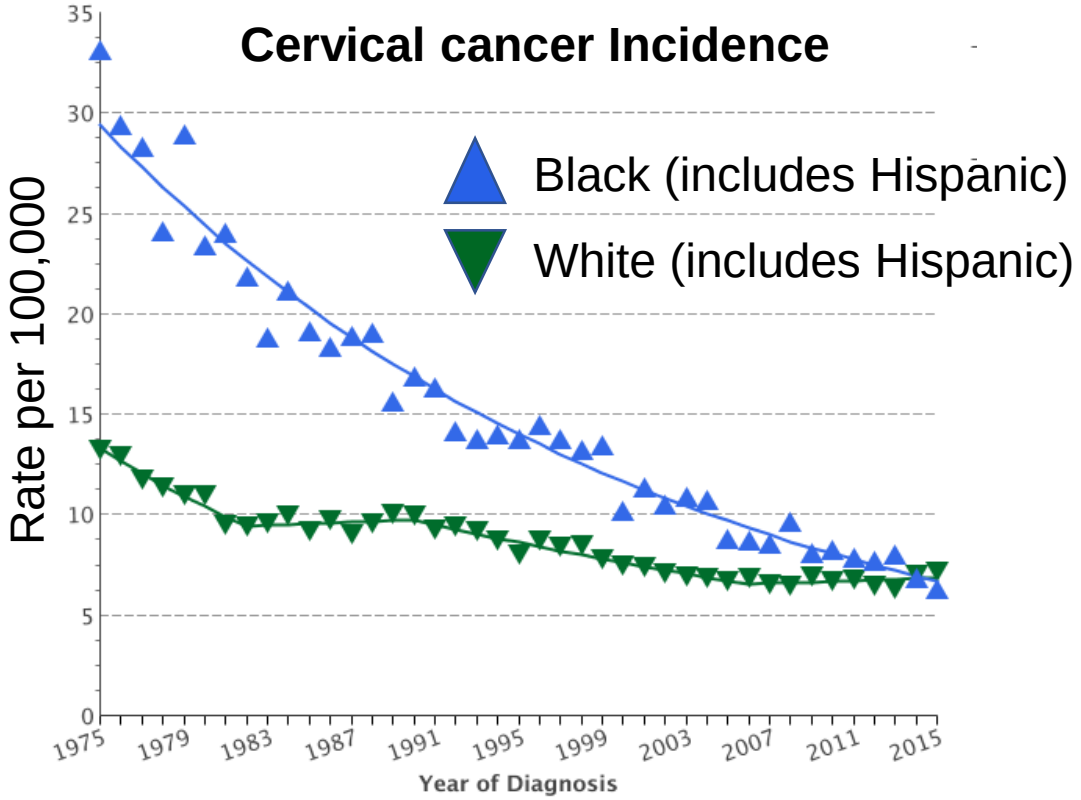
- Enroll a large cohort of patients across all of NCI's clinical trials networks who are undergoing cancer therapy and who test positive for SARS-CoV-2 to characterize factors associated with COVID-19 severity.
- Describe modifications to cancer treatment made due to COVID-19.
- Evaluate the association of COVID-19 with cancer outcomes in clinico-pathologic subgroups.
- Assess anti-SARS-CoV-2 antibody development, cytokine abnormalities, and genetic polymorphisms associated with severe COVID-19.
- Create a bank of clinical data, research blood specimens, and radiological images for future research.

NCCAPS: Measures to Address Site Feasibility Issues

- Informed consent may be done remotely.
- Patients are not required to have any extra visits for this study.
  - Research blood specimens will be collected at the same time blood is drawn as part of regular clinical care.
  - Imaging scans collected for banking are those scans being done as part of clinical care.
- Research blood tests do not require on-site processing.
  - Specimen kits will be provided, including shipping to the biorepository.
- Sites receive full accrual credit for enrollments to Step 1, partial credit for step 0, per the ETCTN, NCORP, and NCTN guidelines.

COVID-19 epidemic may stimulate modified approaches to cancer screening

Using COVID-19 epidemic to help overcome higher cervical cancer mortality rates in Black women



Current mortality rates
ASR* 2012-2016

Black women: 3.5

White women: 2.2

*ASR=Annual Standardized Rate

FDA is willing to consider self-collected vaginal specimens for cervical cancer screening. Could enable screening of "hard to reach" women, which could decrease cervical cancer incidence and mortality.

Thanks to

- Ligia Pinto, Troy Kemp, Jim Cherry: NCI Frederick Serology lab
- Dom Espisito, FNL Protein Expression Lab
- Ned Sharpless, Dinah Singer, Jim Doroshow
- Tony Kerlavage, Stephen Chanock, Neal Freedman, Jonas de Almeda
- Brent Coffey and his FNL team