Overview and History of the NCI FFRDC

NIH NATIONAL CANCER INSTITUTE

Overview

Federally Funded Research and Development Center at Frederick

- Distinctive national resource – the only FFRDC dedicated principally to biomedical research
- Unique, collaborative research and development resource to tackle difficult, urgent and intractable problems that span from basic research to clinical investigations
- Administered by the NCI whose mission it is to help people live longer, healthier lives by supporting research to reduce the incidence of cancer and to improve the outlook for patients who develop cancer
- Together, along with the broader research community, we pursue highly innovative basic, applied, and translational biomedical research

Frederick National Lab for Cancer Research

- The FFRDC operates as the Frederick National Laboratory for Cancer Research (FNLCR)
- The FNLCR, positioned alongside labs at the NCI, provides opportunity for the research community to leverage a unique combination of technical expertise, physical infrastructure, and support services
- The convergence of scientific possibility and the need for more complex partnerships make this an ideal time for the National Lab to underpin the nation's cancer research activities

The Frederick National Lab for Cancer Research

- Partnership with the FNLCR is critical to the NCI
- NCI looks forward to expanding that partnership to provide for greater engagement with the biomedical research community
- Together we can help people live longer, healthier lives by reducing the incidence of cancer and improving the outlook for patients who develop it

Laboratory Directed Exploratory Research Fund

- Up to $1M to fund National Lab pilot projects
- Fund Objectives
  - Enhance the innovation, creativity, originality, and quality of research activities at the National Lab
  - Facilitate collaborations within FNLCR
  - Engage universities and encourage collaboration and strategic interactions
  - Enable demonstration of exploratory “proof of concept” projects which will lead to durable funding through contract or grant mechanisms

History

The NCI's FFRDC – Purpose

- The FFRDC is at the forefront of developing and adapting new technologies and translating basic scientific discoveries into novel agents/approaches/devices for the prevention, diagnosis and treatment of cancer and other diseases, including the Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS), SARS-Cov-2 as well as emerging diseases.

The NCI's FFRDC -- History

- NCI's presence was established in the early 1970's by President Nixon - converting some of Fort Detrick's biodefense laboratories into "a leading center for cancer research."
- In 1975 the FNLCR was designated as a Federally Funded Research and Development Center (FFRDC).
- In 2012 the FNLCR was designated as a National Laboratory.

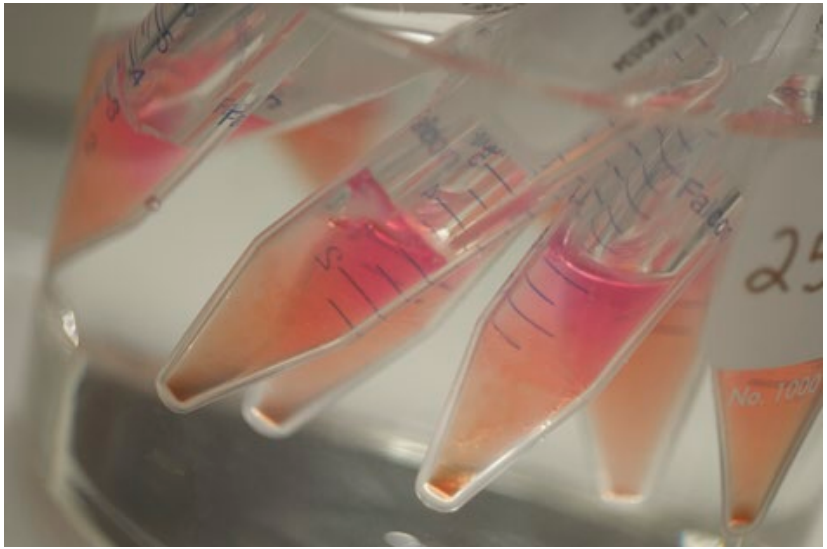
"Where we have previously had scientists…working on weapons of war, we now have scientists devoting their efforts toward saving life…"
President Nixon
Fort Detrick, MD
Oct. 18, 1971

The NCI's FFRDC – History continued

- It is a Government-owned Contractor-operated facility.
- Can perform work for other than the sponsoring agency under the Economy Act.
- The contractor entity is termed the Frederick National Laboratory for Cancer Research (FNLCR).

Over 40 Government Research Centers Share the FFRDC Designation

- Argonne National Lab (DoE)
- Lawrence Livermore National Lab (DoE)
- Los Alamos National Lab (DoE)
- Brookhaven National Lab (DoE)
- Oak Ridge National Lab (DoE)
- National Defense Research Institute (DoD)
- Jet Propulsion Lab (NASA)



FNLCR is the only FFRDC in the nation dedicated solely to biomedical research

FFRDC Defined

- **“Federally Funded Research and Development Centers (FFRDCs) means activities that are sponsored under a broad charter by a Government Agency (or agencies) for the purpose of performing, analyzing, integrating, supporting, and/or managing basic or applied research and/or development, and that receive 70% or more of their financial support from the Government.”**
  - A long-term relationship is contemplated;
  - Most or all of the facilities are owned or funded by the government; and,
  - The FFRDC has access to government data, employees, and facilities beyond that common in a normal contractual relationship.

    (FAR 2.101)

FNLCR – A Unique National Resource

As an FFRDC, the FNLCR provides the NCI with a unique resource to achieve:

Flexibility

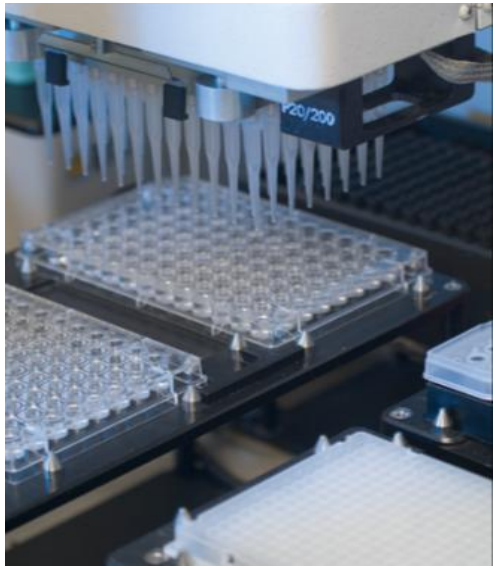
Rapid Response

Increased Efficiency

FNLCR – A Unique National Resource -- continued

Meeting the most urgent biomedical research needs of the nation, including:

- The NCI
- Other NIH institutes
- Other government agencies
- Extramural investigators
- NCI corporate partners



FNLCR – Locations

- Regional
  - Frederick, MD
  - I270 Corridor
  - Bethesda/DC Area
- Nationally
- Internationally
  - North America
  - South America
  - Africa
  - Asia

FNLCR – Research/Research Support Capabilities

- Advanced Computing & Bioinformatics
- Animal Science
- Assay Development & Performance
- Bioengineering
- Biospecimen Processing
- Cell Biology
- cGMP Production Biopharm & Vaccine
- Chemistry
- Clinical Studies Support
- Drug Discovery & Development
- Imaging
- IT Infrastructure & Operations
- Molecular Biology
- Nanotechnology
- Omics
- Pathology
- Repositories
- Structural Biology
- Virology

Summary

The FNLCR is meeting the most urgent and challenging biomedical research needs of the NCI, other NIH institutes, other Government agencies and the extramural community.

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www.cancer.gov/espanol

FFRDC Vision, Goals, and Strategic Program Objectives

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Frederick National Laboratory for Cancer Research

A critical component of the research enterprise

Looking toward the future

FNLCR: One contract, many constituents

FNLCR performs work on behalf of

NCI Divisions, Offices, and Centers

17
NIH Institutes and Centers
Has supported every NIH IC over its history

6
other federal agencies

Typically

Changes over time with strategic scientific needs and demand

~70%
NCI / cancer research

~30%
other biomedical research support

FNLCR Achievements

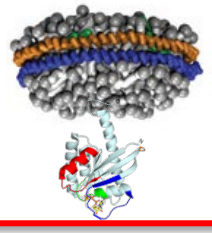
- **Over 400 NIH-sponsored clinical trials per year**
- **Produced over 130 biopharmaceutical products** (over 60 in clinical trials)
- **Produced 70 lots** of clinical products in the last five years through **two cGMP manufacturing programs**
- **Characterized over 440 candidate nanoformulations**
- Developed first test to screen nation's blood supply for HIV

Sample projects supported:

- Cancer Moonshot
- The Cancer Genome Atlas (TCGA)
- NCI Molecular Analysis for Therapy Choice (NCI-MATCH)
- Human Papillomavirus (HPV) Serology Laboratory
- Clinical Proteomic Tumor Analysis Consortium (CPTAC)
- Genomic Data Commons (GDC)
- COVID-19: SeroNet, Serology Validation Program (with FDA), NIAID clinical trials
- Partnership for Research on Ebola Vaccines in Liberia (PREVAIL)
- National Center for Advancing Translational Sciences Therapeutics for Rare and Neglected Diseases (NCATS TRND)

RAS Initiative Collaborations: Hub and Spokes

RAS Initiative "Hub"



14 cCRADAs

12 Strategic Collaborations

5 Industry Collab.

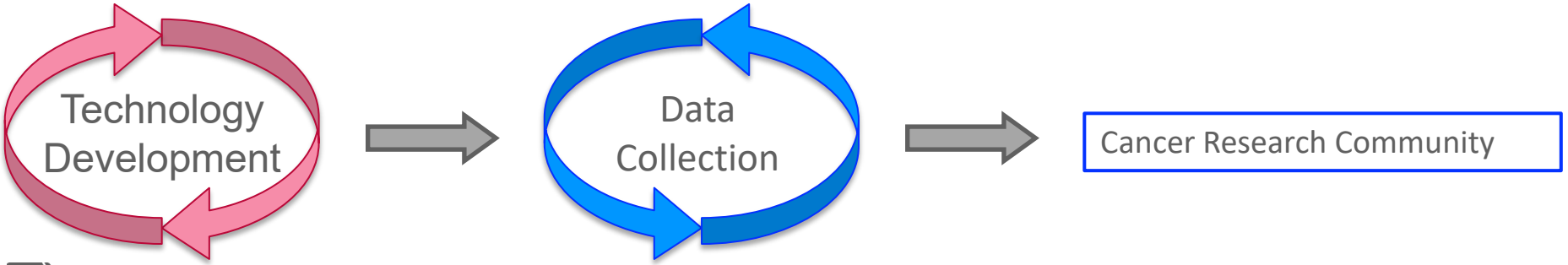
27 Academic Collaborations

National Cryo-EM Facility

Over 550 cancer-related data collections from 39 institutions.

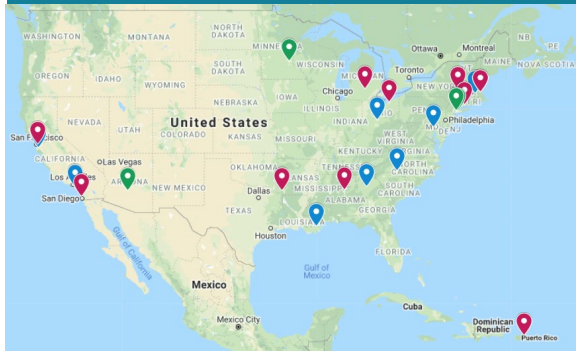
More than 40 NCEF supported publications in journals like Nature, Science, Cell, Nature Communications, PNAS, and NSMB.

Paper in Microscopy Today describing best practices used in the facility.



COVID-19

SeroNet Coordinating Center



CBC Site U54 Site U01 Site

Clinical Serology National Standards

Reference standards for antigen positive plasma

Protein Expression Lab

Provided spike proteins for seroprevalence and other studies. Additionally, screened 2,000 tethering fragments to identify those that bind to active site cysteines in essential proteases.
With Argonne National Lab.

Clinical Trials with NIAID

- ACCT-Remdesivir
- ACTIV-3 part of Operation Warp Speed (inpatient) multiple neutralizing mAb
- ACTIV-2 Outpatient mAb with other therapies
- Mexico, Indonesia, Mali, Liberia, Guinea

NCI/FDA SARS-CoV-2 Serology Validation Program

- Evaluation of ELISA assays and Lateral Flow Devices
- specificity and sensitivity

Serosurveillance Studies with NIH All of Us

Screening 40,000 serum samples for SARS-CoV-2 antigens as a measure of early exposure

Looking toward the future

Vision for FNLCR to advance biomedical research in the future

3

FUNDAMENTAL TASKS

- Provide to NCI-supported investigators access to services, tools, and resources not readily available to individual labs

- Serve as a hub for technology development

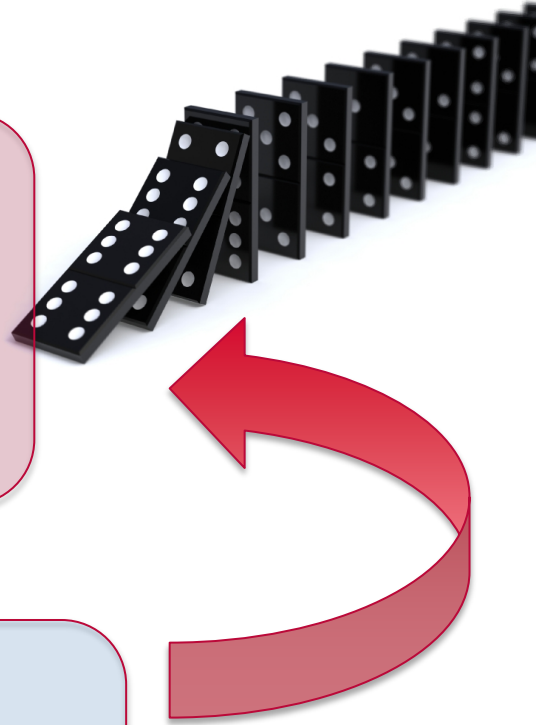
- Function as a nucleus for large-scale projects

Strategic Program Objectives

- All scientific and business capabilities support these strategic program objectives

FNLCR Research Areas and Capabilities

Structural Biology
High-Performance Computing
Chemistry
Biospecimen Processing
Data Science
Assay Development
Omics
Drug Discovery and Development
Animal Sciences



Facilities Operations and Management
Safety and Logistics
Financial Management
Central Supply Warehouse
Human Resources
Acquisition and Purchasing
Program Management
Business Operations

FNLCR goals and operating principles

Pursue **high risk/high reward projects**

Build **relational bridges** and work as a team with partners for **shared success**

Maintain a **full intellectual, scientific partnership** with the NIH

Operate in a **flexible**, **transparent**, **accountable** and **effective** manner

Demonstrate **boldness and creativity** in ideas and execution

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National Mission Programs

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National Mission Program: The RAS Initiative

NIH NATIONAL CANCER INSTITUTE

The First National Mission Program: The RAS Initiative

- National Mission Programs undertake important and ambitious projects in cancer research that would be difficult to pursue without an orchestrated, multidisciplinary effort
- The RAS Initiative was launched in 2013 to target oncogenic RAS:
  - RAS (KRAS, NRAS, HRAS) is the most frequently mutated gene family in cancer (30% of all tumor types)
  - KRAS mutations are know drivers in 3 of the most lethal cancers: lung, colorectal, and pancreatic cancers
  - RAS was considered an "undruggable" therapeutic target for 30+ years
- The RAS Initiative primary goals:
  - Seek greater understanding of oncogenic RAS in cancer biology and disease
  - Build an open collaboration model across government, academia, and industry researchers to reenergize efforts to discover RAS therapeutics

RAS Initiative Hub and Spoke Model

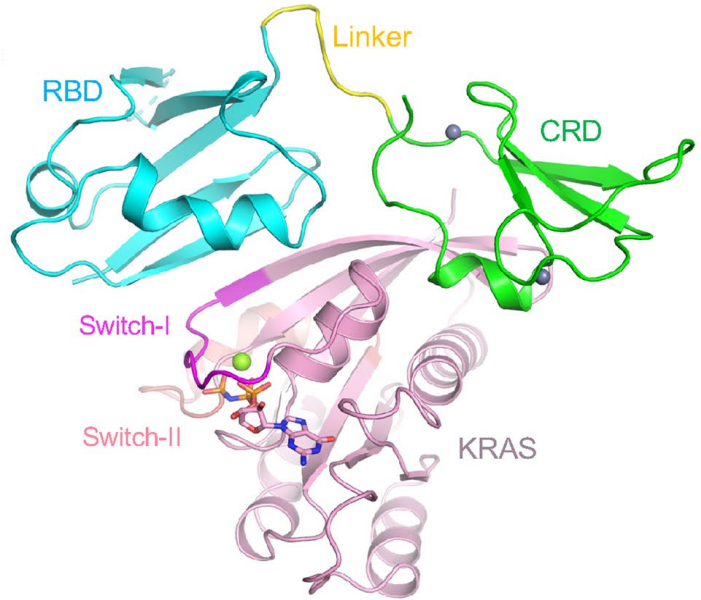
- The Frederick National Laboratory for Cancer Research (FNLCR) acts as the **hub** that connects to the larger community of RAS researchers around the world combining efforts and creating new ways to approach the complex issue of RAS (**spoke**).
- Renowned RAS researcher Dr. Frank McCormick serves as the Scientific Advisor
- Core ongoing research capabilities include:
  - Biochemistry and Structural Biology
  - Molecular Dynamics and

    Structure-based Drug Design
  - RAS Resources and Interactions
  - RAS Outreach

Biochemistry and Structural Biology

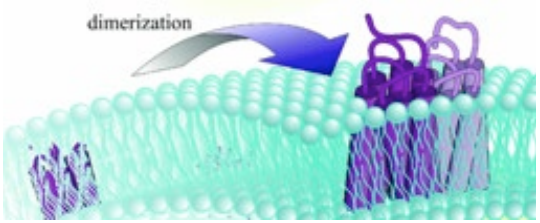
- State-of-the-art proteomics facility supports top-down protein analysis of intact proteins and their modified proteoforms can be precisely mapped to include mutation linkages and post-translational modification stoichiometry
- Structural biology supports both target identification and structure-based drug design using X-ray crystallography, NMR, and cryo-EM
- Structures solved include:
  - Full length KRAS
  - Oncogenic KRAS mutants
  - KRAS in complex with effectors (RAF-1)

  and regulatory proteins (SPRED1-Neurofibromin)
  - KRAS/small molecule holo structures

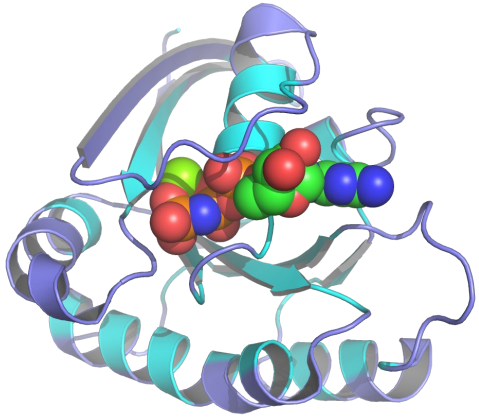


Molecular Dynamics and Structure-based Drug Design

- RAS structure and dynamics in cellular membranes program:
  - Goal to create multiscale computational framework that uses experimental input data from live cells
  - Explore conformations and dynamics of RAS proteins alone, as dimers, or in complex with effectors
  - Macroscale simulations of RAS behavior in membranes based upon local lipid composition



- Small molecule therapeutic development
  - Fragment-based drug design
  - Structure-based drug design
  - Covalent and non-covalent inhibitors
  - Allosteric inhibitors



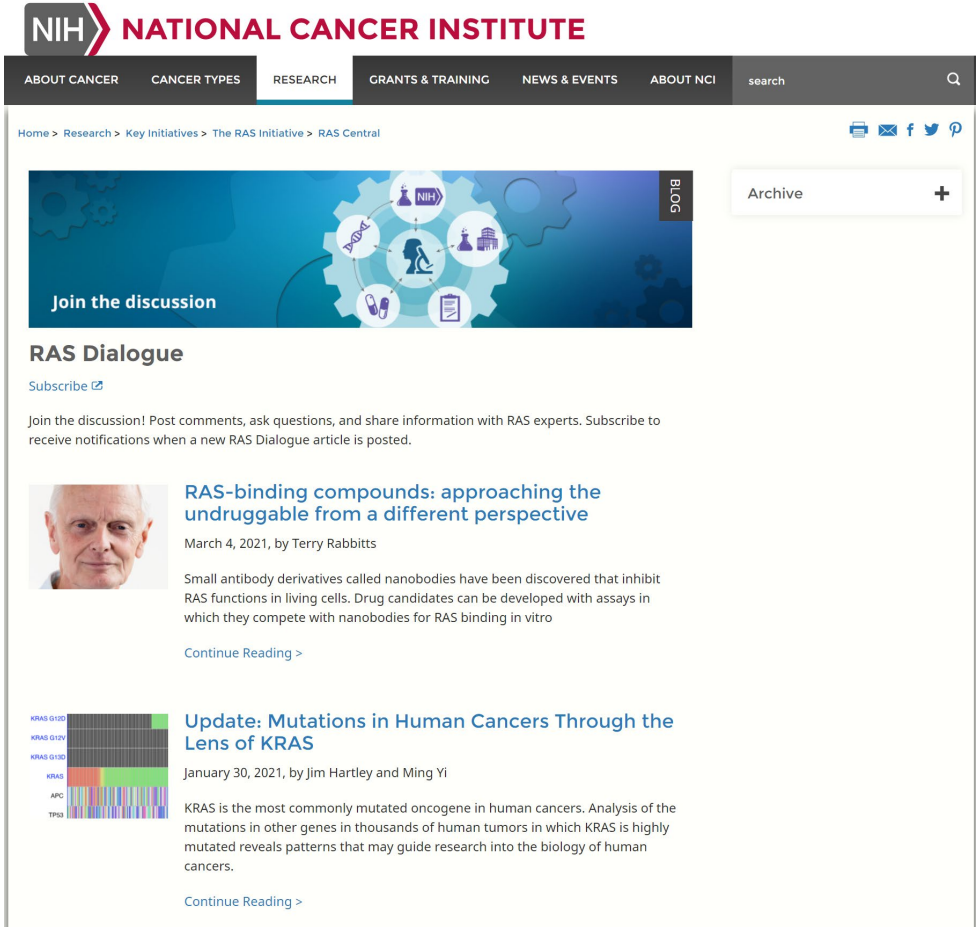
RAS is druggable!

RAS Initiative: Resources and Interactions

- RAS Reagent Core generates reagents to support all FNLCR projects and assist external scientists as well
  - 552 Universities and NPOS
  - 10,067 plasmids and vectors (Via Addgene)
  - 1,946 individual RAS and RAS pathway plasmids
  - 19 complete RAS pathway kits (360 plasmids/kt)
  - 21 complete RAS mutant kits (61 plasmid/kit)
  - 820 cells lines
- Collaborations
  - 27 Academic Institutions
  - 12 Strategic (National Labs, Advocacy, NIH)
  - 10 Industrial partners

- Community Outreach
  - 2 RAS Symposia (3rd May 2021)
  - 8 RAS Community Workshops
  - 4 AACR/NCI Special Sessions Presentations
  - Participation in NCI Ras Synthetic Lethality Network
  - 40+ publications

RAS Outreach – Cancer.gov/RAS



- The RAS Initiative sends email updates >4,200 international researchers conducting RAS-related studies
- The Initiative has held workshops of topical interest to gain input from extramural experts
- In May 2021, the FNLCR is hosting the third community-wide RAS Initiative Symposium (Virtual)

RAS Outreach – RAS Lab

- RAS Lab - an invitation only discussion forum to promote technical scientific exchange among RAS researchers
- RAS Lab allows members to post and respond to messages, upload data, and contact one another for collaborations
- Currently, more than 1,085 members are involved in the discussion

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National Mission: Cryo-Electron Microscopy

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National Cryo-Electron Microscopy Program

- Mission: Improve the accessibility of cryo-EM techniques to the cancer biology community & optimize cryo-EM techniques and workflows
- National Cryo-EM Facility: *2017 - present*
  - Extramural user access to cutting-edge cryo-EM data collection
  - Identified 3 user groups:
    1. Cryo-EM experts lacking access to advanced instrumentation
    2. Structural biologists in adjacent disciplines
    3. Cancer biologists with no structural biology experience
- Cryo-EM Research and Development: *2019 - present*
  - Exploring new experimental platforms
  - Methods and technology development for cryo-EM field

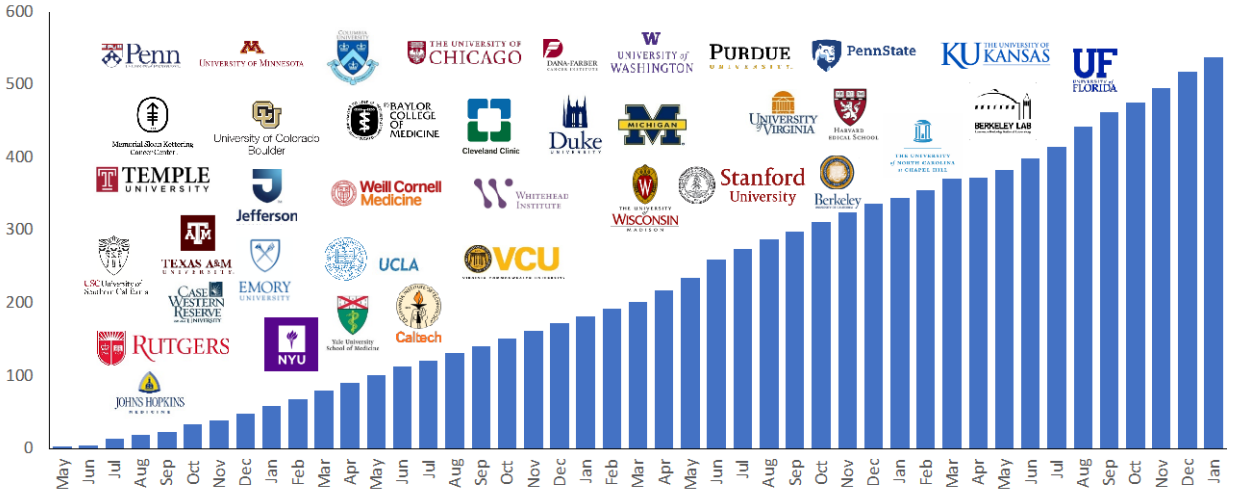
National Cryo-Electron Microscopy Facility

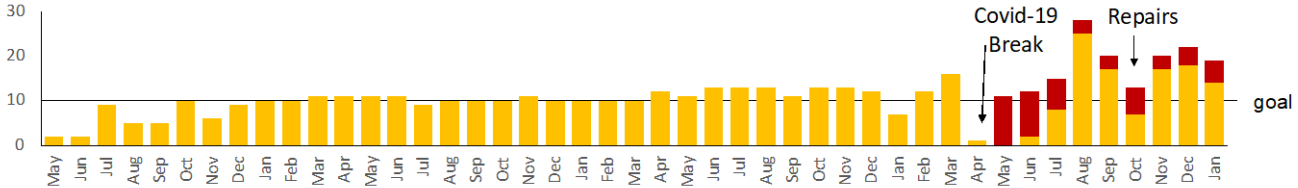
- Collect cryo-EM data on specimen grids provided by academic cancer researchers; transfer data to client for analysis
- Clients do not need to be NCI grantees
- Two Titan Krios microscopes
  - Falcon 3EC and K3 BioQuantum detectors.
- Four workstations
- ~240 data collections per year and growing

NCEF Titan Krios Microscope

National Cryo-EM Facility - *the first 4 years*

- 550+ cancer-related data collections from 100+ PIs at 50+ institutions. Feedback is very positive.
- From May, prioritizing COVID-19 related data collections.
- 40+ NCEF supported publications in journals like Nature, Science, Cell, Nature Communications, PNAS, and NSMB.
- Paper in Microscopy Today describing best practices used in the facility.

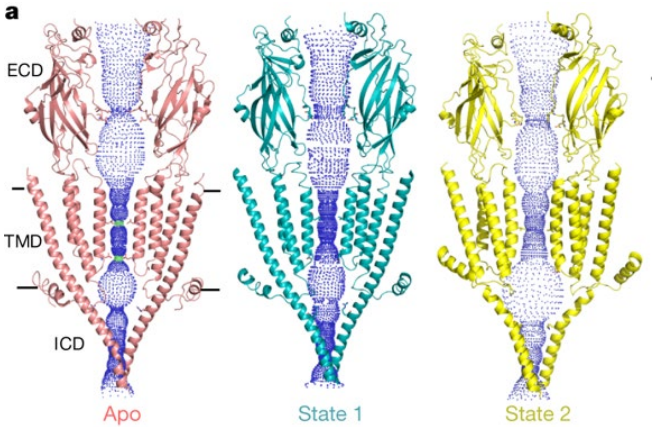




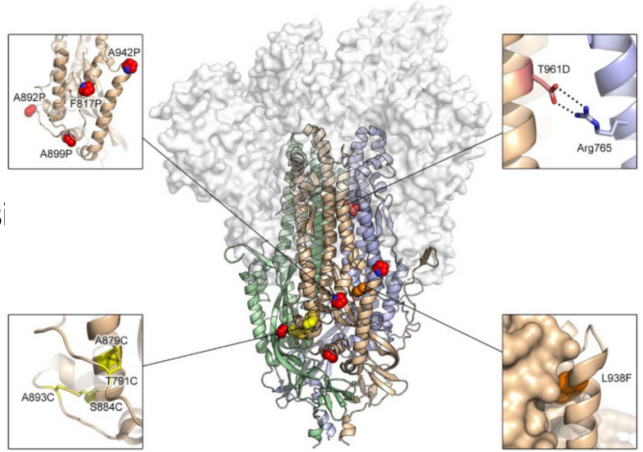
Yellow = Cancer Projects
Red = Covid-19 Projects

NCEF User Successes - Examples

- **Dr. Sudha Chakrapani (Case Western)**
  Serotonin receptor ($5\text{-}HT_{3A}R$)
- **Serotonin receptors regulate gut movement**
- **5-HT are drug targets for anti-emetics**
- **Result: 3.3 Å structure**
- **Published: Basak S et al. (2018) *Nature* 563, 270**



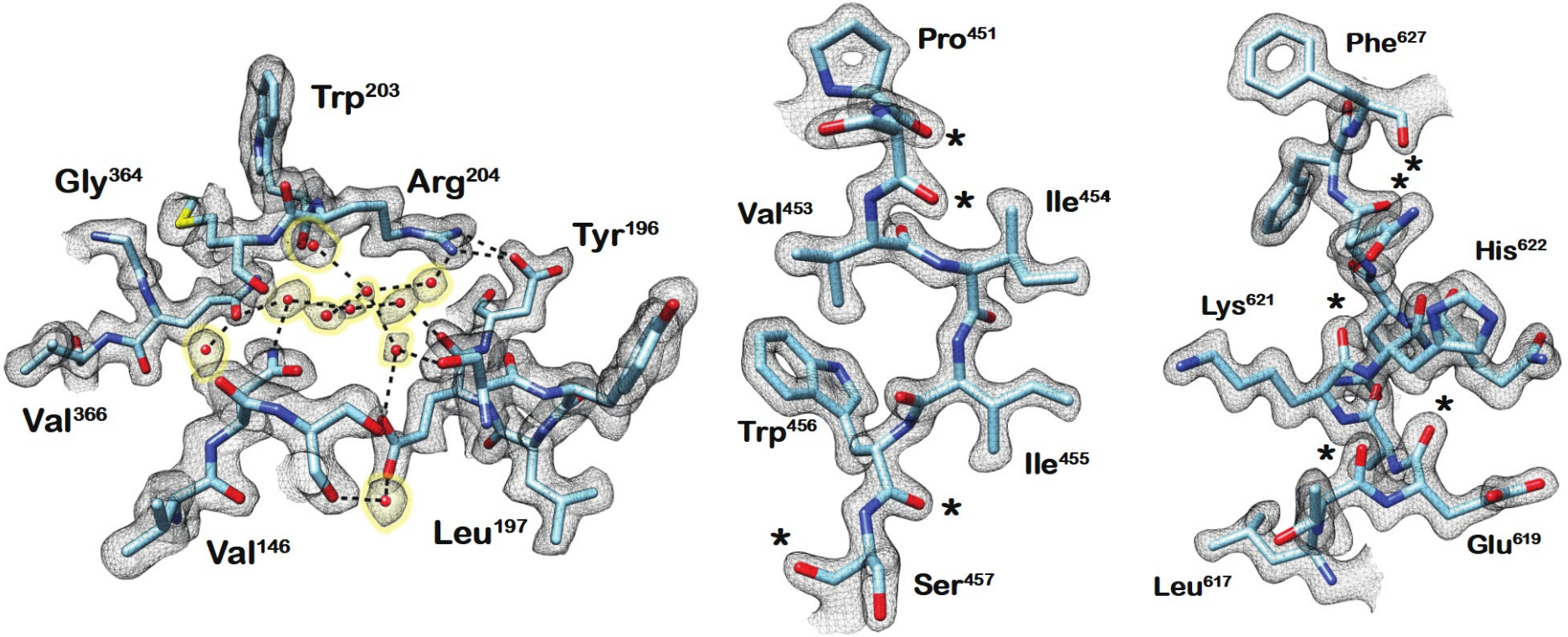
- **Dr. Jason McLellan (UT Austin)**
  SARS-CoV-2 spike protein
- **Receptor and fusion protein of SARS-CoV-2**
- **Stabilized version of the protein to be used in new vaccine des**
- **Result: 3.2 Å structure**
- **Published: Hsieh et al. (2020) Science**



Cryo-Electron Microscopy R&D

- Explore alternative techniques, platforms, and workflows to accelerate the development of next-generation cryo-EM tools and to reduce costs
- Thermo Fischer Glacios
  - Falcon 3 & 4, Ceta-D, DE-64 cameras
  - 2.1 Å resolution
- JEOL CryoARM 200
  - Gatan K3 camera
  - 1.8 Å resolution
- Sample preparation equipment; four workstations; structural analysis software

JEOL CryoARM 200 β-galactosidase at 1.8 Å resolution



3,618 total H_20 molecules

Merk et al., IUCrJ (2020)

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Serological Sciences Program

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National Mission Programs

NCI's Serological Sciences Program

- NCI's Serological Sciences Network and *Clinical/Translational Serology Taskforce*

NCI COVID-19 Response

FOUNDATIONAL SEROLOGY

Serological Sciences Network (SeroNet)

- 8 Centers of Excellence
- 13 Research Projects
- 4 Capacity Building Centers
- FNL Serology Lab & Network Coordinating Center

CLINICAL & TRANSLATIONAL SEROLOGY

Sero-protection Studies:
- Mount Sinai, University of Arizona
- NIH All of Us
- NCI SEER + Health Verity

COVID-19 Seroprevalence Studies Hub (SeroHub)

Antibody test performance evaluation, with FDA

Standard reference serum

Clinical trials for COVID-19 therapeutics
- BTK inhibitors
- Tocilizumab

SUPPORT FOR CANCER RESEARCH AND CARE AMID THE PANDEMIC

NCI COVID-19 in Cancer Patients Study (NCCAPS)

Flexibilities for grantees

Clinical trials adaptations

Modeling to predict long-term cancer outcomes

ADDITIONAL COVID-19 RESEARCH

- Excess Mortality Study
- Digital Health Solutions (with NIBIB)
- ACTIV (trans-NIH)

SeroNet: NCI's Serological Sciences Network for COVID-19 Response

National Institute of Allergy and Infectious Diseases

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SeroNet

A network of researchers who collaborate to create new assays to measure the immune response to infection and gain further understanding of response variation and duration.

CDC

RS FOR DISEASE
L AND PREVENTION

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.

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

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

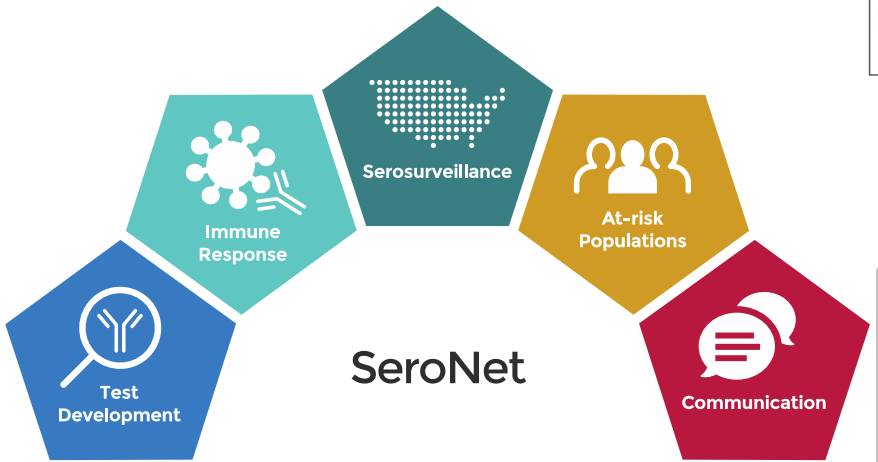
SECTION 1. SHORT TITLE.

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

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.



Coronavirus (COVID-19) Update: Serological Test Validation and Education Efforts

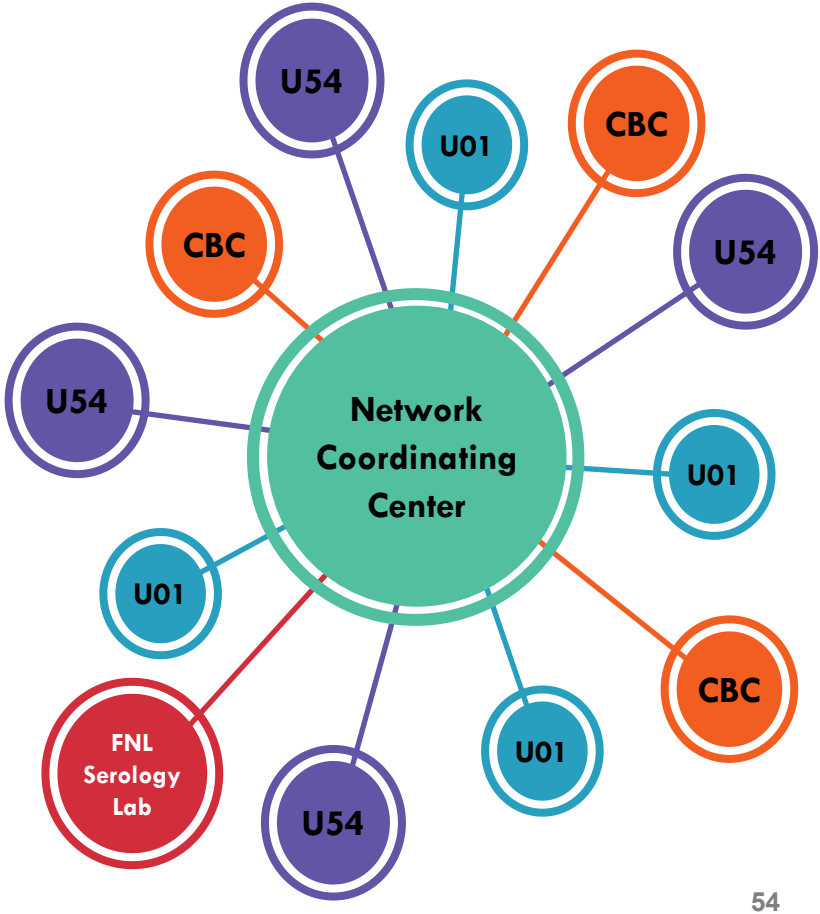
Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy

Frederick National Laboratory for Cancer Research
sponsored by the National Cancer Institute

The Frederick National Laboratory for Cancer Research and COVID-19 serology testing

Goals of the Serological Sciences Network (SeroNet)

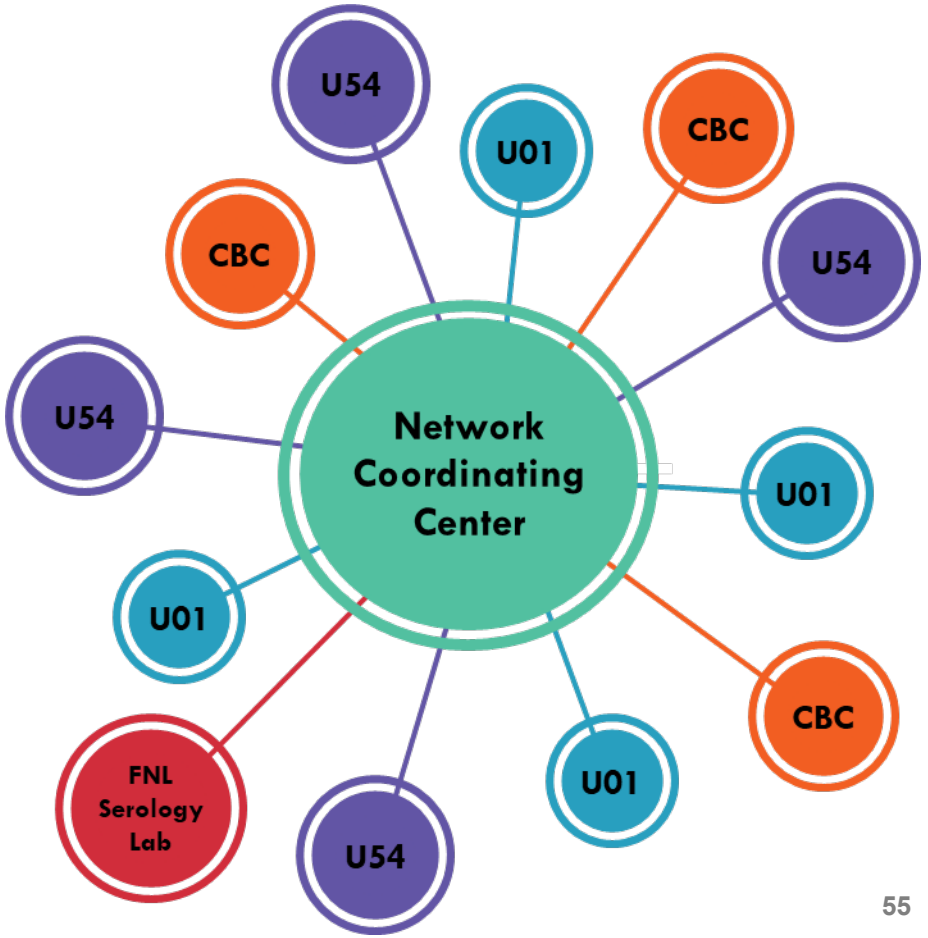
- **Conduct basic and applied foundational research into SARS-CoV-2 immune response**
  - Understand the mechanisms driving the innate, humoral, and cellular immune responses
  - Determine the host, genetic, and environmental modifiers of the immune response
  - Determine the serological correlates of disease pathogenesis and protection against future infection
  - Define access, communication, and implementation barriers related to SARS-CoV-2 serological testing
- **Develop assays, national reference standards and antigens, multiplex assays**
- **Develop high-throughput testing capability and guidelines available to the scientific community**
- **Create a collaborative network of investigators that can make rapid progress and make data widely available**



The NCI's Frederick National Lab for Cancer Research (FNLCR)

-Unique Participant in SeroNet

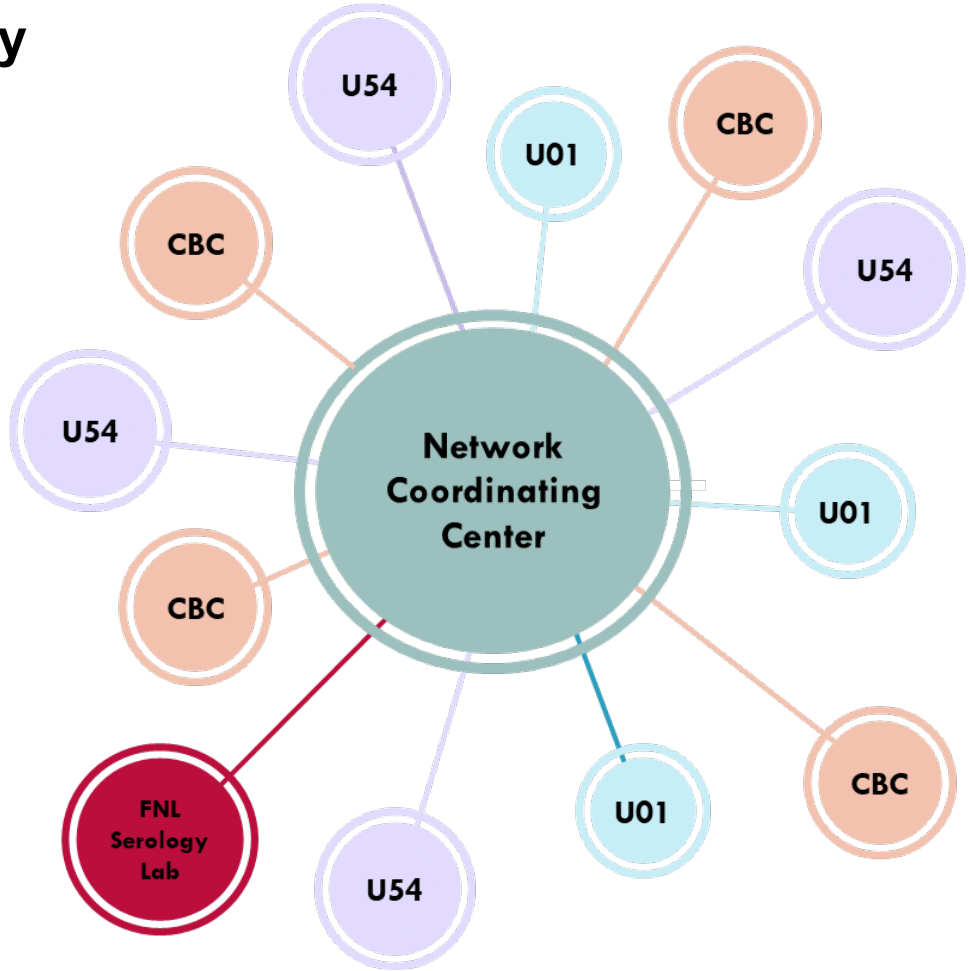
- Capacity Building Center Subcontracts
- Network Coordinating Center
- FNL Serology Lab



The NCI-FNLCR Serology Laboratory

Main Goals:

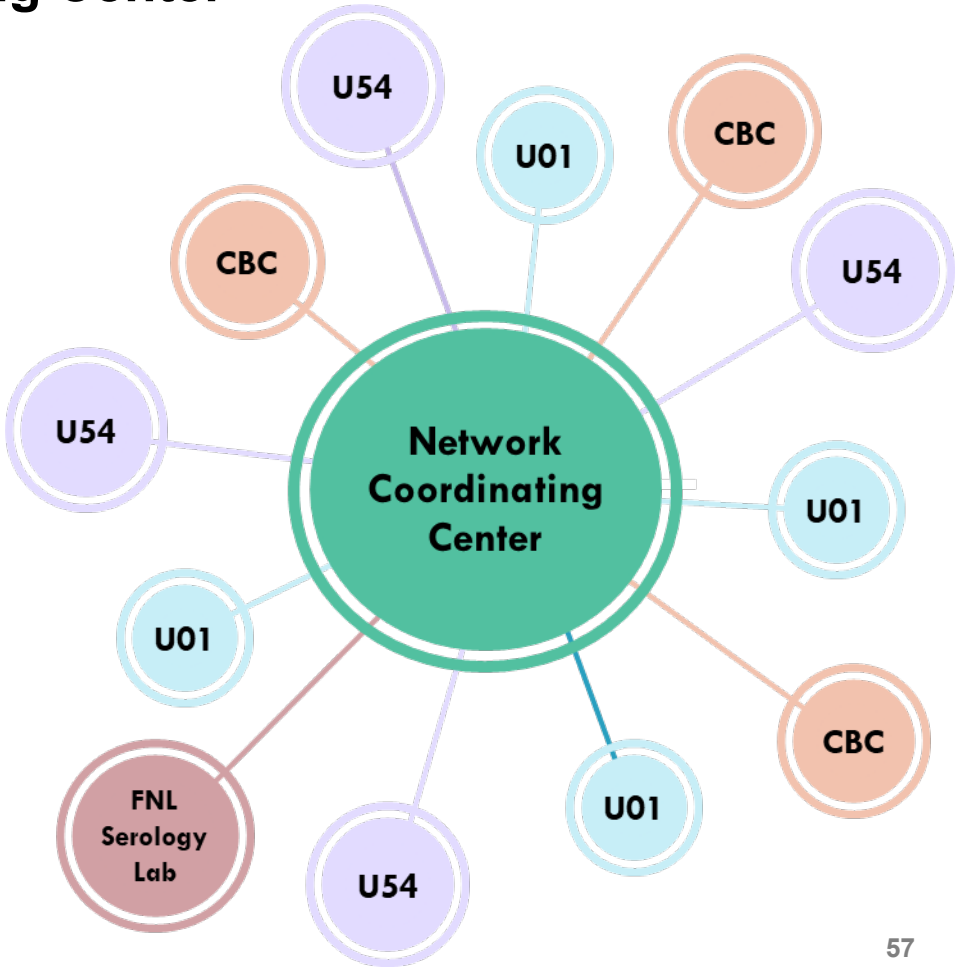
- **Implement and qualify SARS-CoV-2 ELISA assays for IgM and IgG and**
- **Build validation and proficiency panels for assay development and validation**
  - Rapidly identify, procure, and characterize serum/plasma specimens from SARS-CoV-2 patients and necessary controls to identify negative, medium and high response
- **Produce assay standards and reference reagents (antigens) for qualification/validation of SARS-CoV-2 serological and other relevant immune assays and distribute to the network**
- **Implement standardized testing capability to support cancer research and vaccine trials**
- **Evaluation of determinants of neutralizing responses**
- **Partnership with regulatory bodies and assay developers for validation of serology testing platforms**



The NCI-FNLCR Network Coordinating Center

Main Goals:

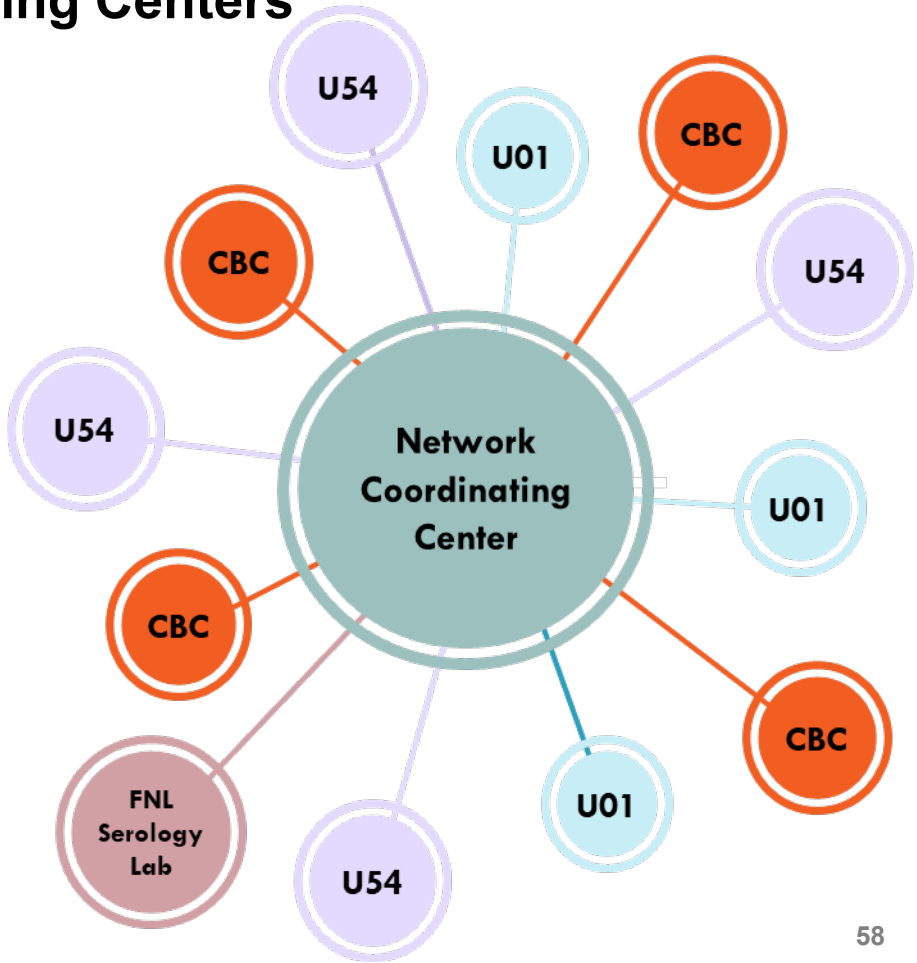
- Provide program management, coordination and communication across the Serological Sciences Network for SARS-CoV-2
- Coordinate sharing of the data, reagent, sample, and assays
- Coordinate comparison of results among different centers and assays through inter-Center collaborative studies, leading to international serology standardization
- Coordinate partnerships with national and international associates such as the FDA, CDC, WHO, NIAID National Institute for Biological Standards and Control (NIBSC), and others



SeroNet: NCI-FNLCR's Capacity Building Centers

Main Goals:

- **Acquire and conduct** quality control assessments of critical reference samples; (National Reference)
- **Develop and validate** scalable serological testing capability for SARS-CoV-2 infection
  - using a high-quality serological assay, with high specificity and sensitivity, >94%
- **Scale up** high quality serological testing to meet the emerging need for nation
- **Collaborate in** serosurveillance and sero-protection studies for post vaccinated individuals
- **Conduct focused studies** in serological sciences technology development



Components of the Serological Sciences Network (SeroNet)

- Geographical Distribution of SeroNet Sites

- **4 CBCs**: Serological Sciences Capacity Building Centers
- **8 U54s**: Serological Sciences Centers of Excellence (RFA)
- **13 U01s**: Serological Sciences research projects (RFA)
- NCI-Frederick **Serology Laboratory**
- **Network Coordinating Center** at NCI-Frederick

SARS-CoV-2 Clinical Translational Serology Task Force:

-Trans-Governmental Collaborative Effort to Independently Evaluate SARS-CoV-2 Serology Assays

Mission:

To **catalyze translation of research** findings into **public health** changes by bringing together and engaging **various government organizations**, **academic groups, and industry partners** to provide relevant tools and information related to serology testing to **help decision makers manage** the current and future status of the SARS-CoV-2 pandemic.

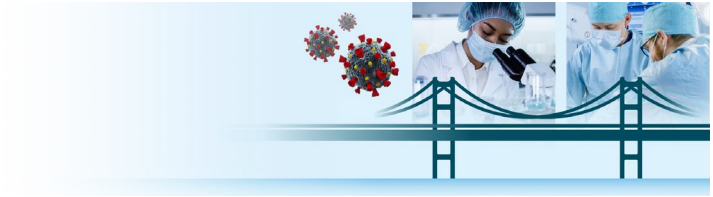
Objective: Work with academics, industry, regulatory bodies, and policymakers to identify gaps in serology testing
Implement use of standards to harmonize testing and Identify the most appropriate assays for clinical testing
Foster national and international collaborations with clinical and public health organizations, including WHO
Promote public education about serological sciences and public health value

Impact:

- Enable development of **reliable, accurate and reproducible** methods
- **Comparisons of data** between different laboratories
- Accelerate implementation of **harmonized assays, new vaccines and new vaccine recommendations**

Partners:

BARDA	**National Institutes of Biological Standards and Control**
CDC	**(NIBSC)**
FDA	**WHO**
NCI-Frederick	**Mount Sinai**
NIAID	**Columbia University**
NIH-CC	**University of Maryland**



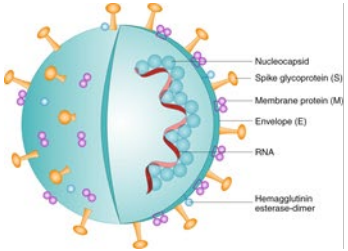
SARS-CoV-2 Serology Validation Program:

- Workflow of Performance Evaluation of ELISA Kits and Lateral Flow Devices at FNLCR

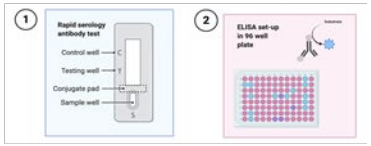
- **HHS agencies collaborative effort includes FDA, CDC, NIAID, BARDA, and several academic groups (Columbia, Mount Sinai, Northwestern) and NCI's cancer centers**
- **<u>Goal</u>: Performance evaluation of both ELISA assays and Lateral Flow Devices to assist the FDA in determining suitability for EUA approval, so only top performing assays with the highest specificity and sensitivity would be available to meet nations testing capacity**

Validation Panels
- **Sample Sources:** Mount Sinai, BEI, Northwestern and Vitalant
- **Composition: sera/plasma**
  - 30 PCR+ patients
  - 70 pre-pandemic controls
  - 10 HIV-positive
- **Sample Characterization and Validation:** CDC,NIAID and NIH-CC

Assays
~ 350 commercial assays to date have been sent to the FNLCR for evaluation of performance



Daily analysis at FNLCR
Following data entry/QC, data is shared with FDA & CDC



FNLCR Assay Validation

120 assays were tested using validation panel

~350 commercial assays await to be validated at NCI-Frederick

FDA Website:
Coronavirus (COVID-19) Update: FDA Publicly Shares Antibody Test Performance Data From Kits as Part of Validation Study

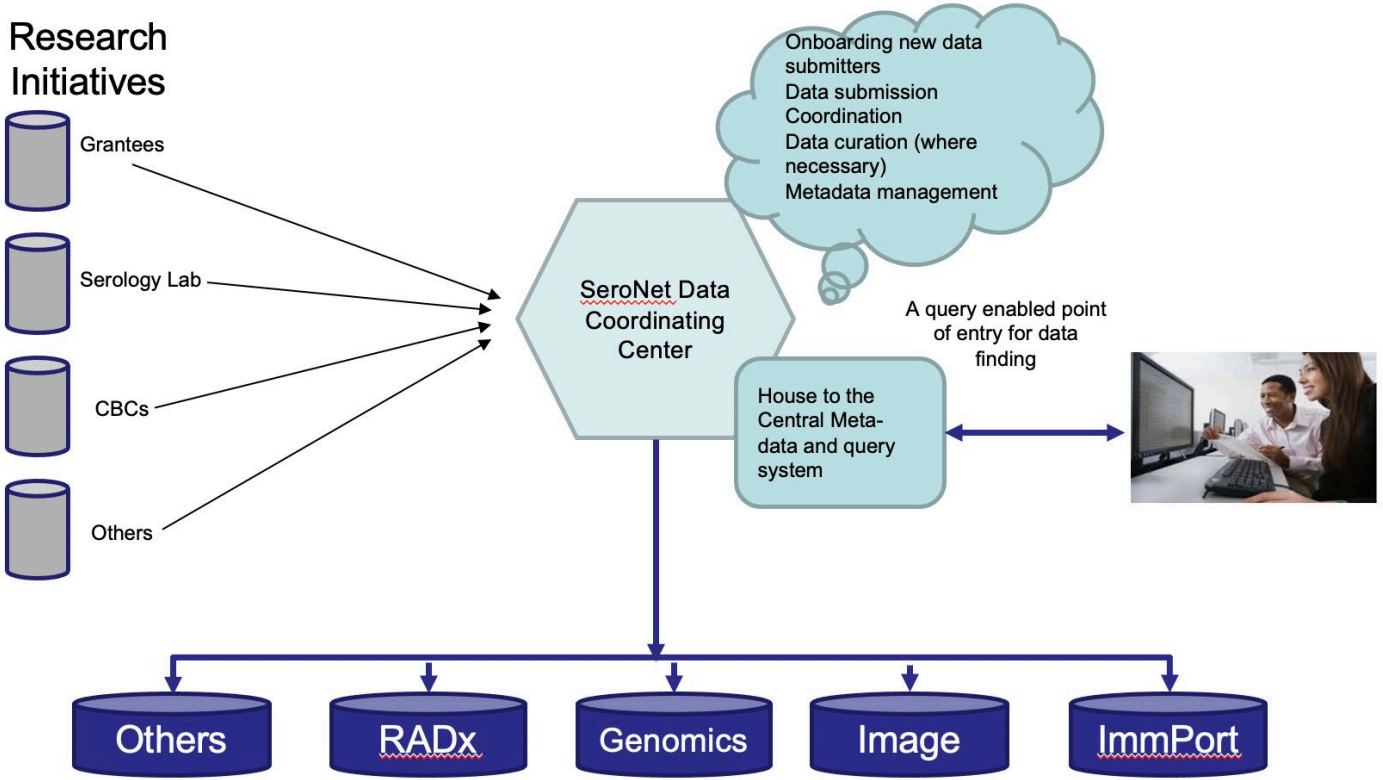
* Evaluation/Reporting of SARS-CoV-2 serology assays in collaboration with FDA, CDC and NIAID, to define assays with the highest performance (sensitivity, specificity and reproducible) to use to determine past exposure to the virus

The utility of serology tests depends entirely on their performance characteristics

SARS-CoV-2 post-vaccine surveillance studies
- cancer/immunocompromised individuals

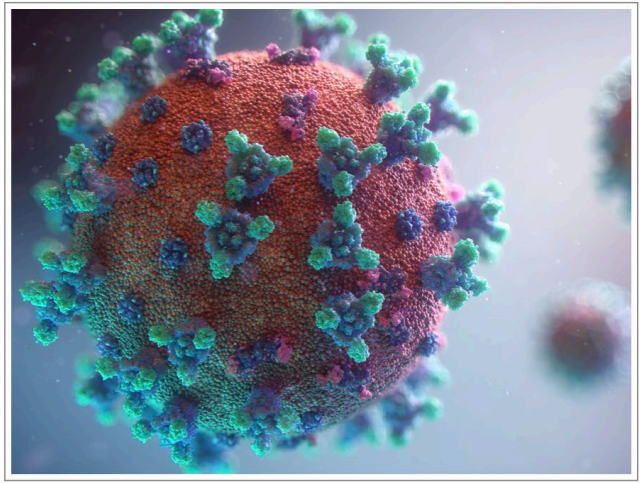
- Develop a common study template design, for “all” vaccination/- serosurveillance studies in cancer/immunocompromised patients
- Establish Baseline predictive factors for COVID 19 course and/or vaccination response
- Response (antibodies/cellular immunity) to vaccine or infection in general cancer populations
- Response in relation to specific therapies (immunotherapy/chemotherapy/molecular targeted therapies/radiation therapy/ surgery/combination therapies)
- Priorities for recommendations: Specimen collection timepoints and patient data elements.

SeroNet Data Coordination by FNLCR



SARS-CoV-2 Serology Standard

Request the Human SARS-CoV-2 Serology Standard



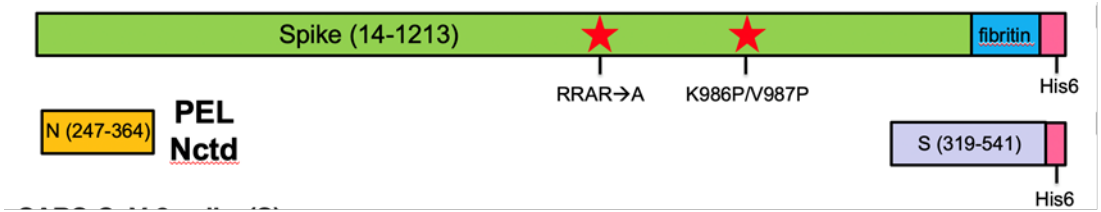
The Human SARS-CoV-2 Serology Standard is a pool of plasma from four blood donors with antibodies (IgM and IgG) to the SARS-CoV-2 spike and nucleocapsid proteins. This US standard will be calibrated to the WHO International Standard as soon as it becomes available. Furthermore, this standard has been assigned ligand binding assay units and neutralizing units based on a collaborative study from eight different laboratories and several types of assays (automated chemiluminescence assays, manufacturer developed ligand binding assays, in-house developed ligand binding assays, and fluorescence reduction neutralization assay).

This serology standard is to be used for calibration purposes by laboratories conducting SARS-CoV-2 serology testing, rather than for routine inclusion as a quality control. The main goal of a serology standard is to harmonize assays that measure anti-SARS-CoV-2 antibodies and to enable comparisons between different studies, including different candidate vaccines. To request the Human SARS-CoV-2 Serology Standard, please fill out the attached form and submit to SSNCCbiospecimens@nih.gov.

Download the request form

- To be used for calibration by labs conducting SARS-CoV-2 serology testing to harmonize assays and enable comparisons between studies
- Pool of plasma with antibodies to SARS-CoV-2 assigned binding and neutralization units based on a collaborative study from eight different laboratories
- Will be calibrated to the WHO standard as soon as it becomes available

SARS-CoV-2 Recombinant Protein for Serology Assay Development



- **Spike [Mt. Sinai, S-2P(14-1213)-His6]**
  - "wild type"
  - D614G
  - B.1.1.7
  - B.1.351
  - B.1.1.28 (K417T)
  - B.1.429
- **RBD [Mt. Sinai, S(319-541)-His6]**
  - "wild type"
  - N501Y (B.1.1.7)
  - K417N/E484K/N501Y (B.1.1.28n, B.1.351)
  - E484K
  - L452R (B.1.429)
  - Y453F (B.1.1.298)
  - K417T/E484K/N501Y (B.1.1.28t)

- **Spike [McLellan, S-2P(14-1208)-3C-His8-S2x2]**
  - "wild type"
  - D614G
  - N501Y/D614G
  - B.1.1.7
  - B.1.351
- **RBD [Ragon, S(318-529)-3C-His8-SBP]**
  - "wild type"
  - N501Y (B1.1.7)
  - K417N/E484K/N501Y (B.1.1.28n, B.1.351)
  - E484K
  - L452R (B.1.429)
  - Y453F (B.1.1.298)
  - K417T/E484K/N501Y (B.1.1.28t)

Protein in inventory
March purification
April purification

- SARS-CoV-2 Spike and RBD proteins, including variants of broad interest, available to all SeroNet institutions
- Large quantities and new constructs can produced through Technical Service Agreements with SeroNet institutions

Impact of the NCI Serological Scientific Activities:

How will this Initiative Contribute to Eliminate the Coronavirus Pandemic?

Investigate immune responses to infection, and vaccines

Develop and validate new methods for laboratory markers of protection

Monitor immunity in clinical trials and pre-clinical studies

Provide evidence to inform new trials and create tools to enable public health changes

Understanding how the host respond to the virus, how vaccines work and correlates of protection

Providing evidence to move forward with new trials for novel vaccine recommendations

Leading an international serology standardization initiative to enable reliable measurement of laboratory markers of immunity and vaccine effectiveness

www.cancer.gov

www.cancer.gov/espanol

Questions?

All questions must be entered into the WebEx chat