

# Frederick National Laboratory Operations and Additional Updates

Frederick National Laboratory  
for Cancer Research

*sponsored by the National Cancer Institute*



**Ethan Dmitrovsky, M.D.**

**President, Leidos Biomedical Research and Laboratory  
Laboratory Director, Frederick National Laboratory for Cancer Research**

DEPARTMENT OF HEALTH AND HUMAN SERVICES • National Institutes of Health • National Cancer Institute

Frederick National Laboratory is a Federally Funded Research and Development Center operated by Leidos Biomedical Research, Inc., for the National Cancer Institute

# Session Objectives

- **Review the Frederick National Laboratory rapid response to the pandemic. This is a case study for a Federally Funded Research and Development Center.**
- **Show that this pivot did not prevent decisive quantitative or discovery science, translational research, and clinical trials.**
- **Cite NCI and NIAID programs with major recent progress.**
- **Answer your questions.**

# Federally Funded Research and Development Center Operations

## **Federally Funded Research and Development Center Contract**

### **Task Order Portfolio:**

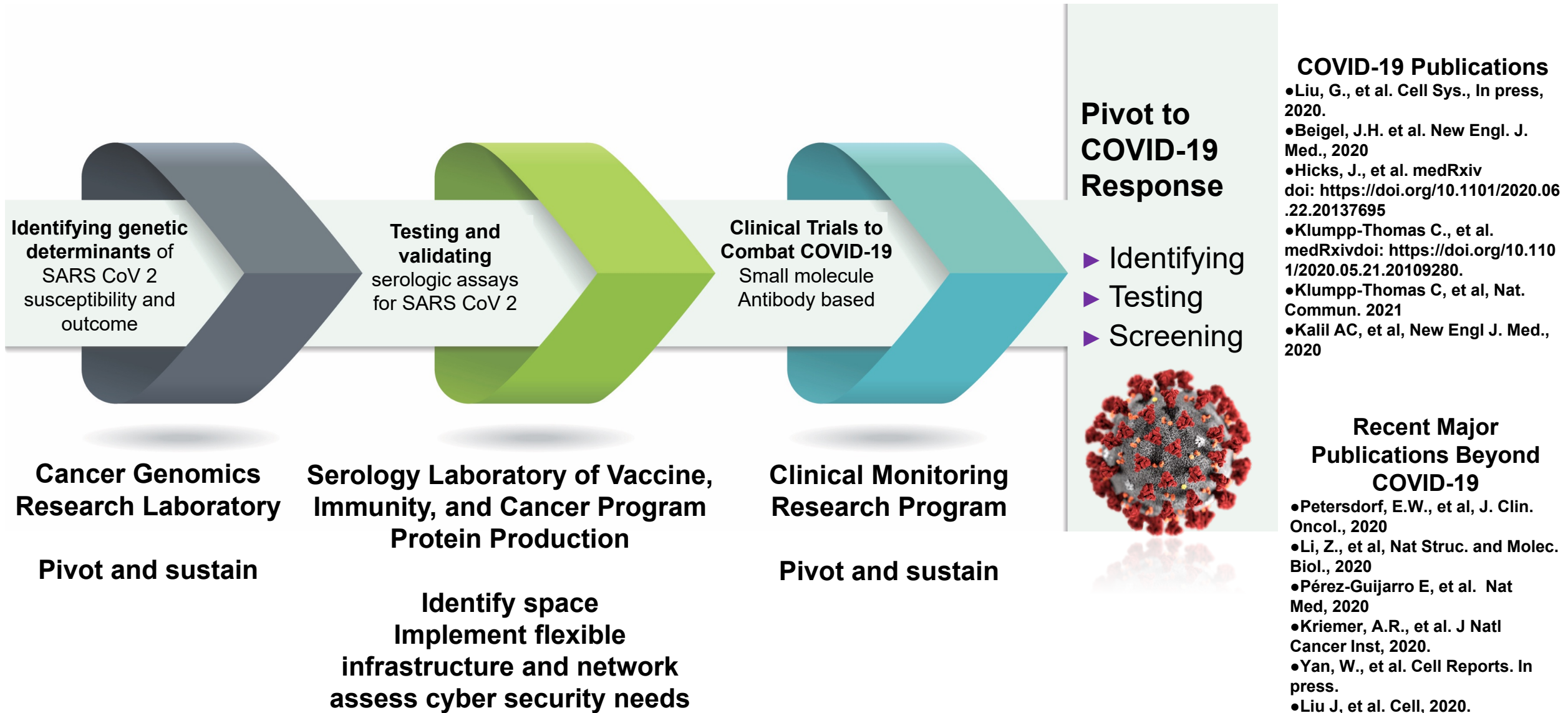
- **5 Operational Task Orders - Benefits of services are recurring with annual funded appropriations.**
- **NCI Task Order, 3 NIAID Task Orders, 1 Lease Task Order**
- **98 are Non-operational Task Orders**
- **38 are in Clinical Group**
- **47 are in Scientific Group**
- **13 are Facility or Infrastructure Refurbishments Task Orders**
- **Extensive outreach to the broader research community is through subcontracting.**



# Frederick National Laboratory Pivot with National Cancer Institute to Combat COVID-19

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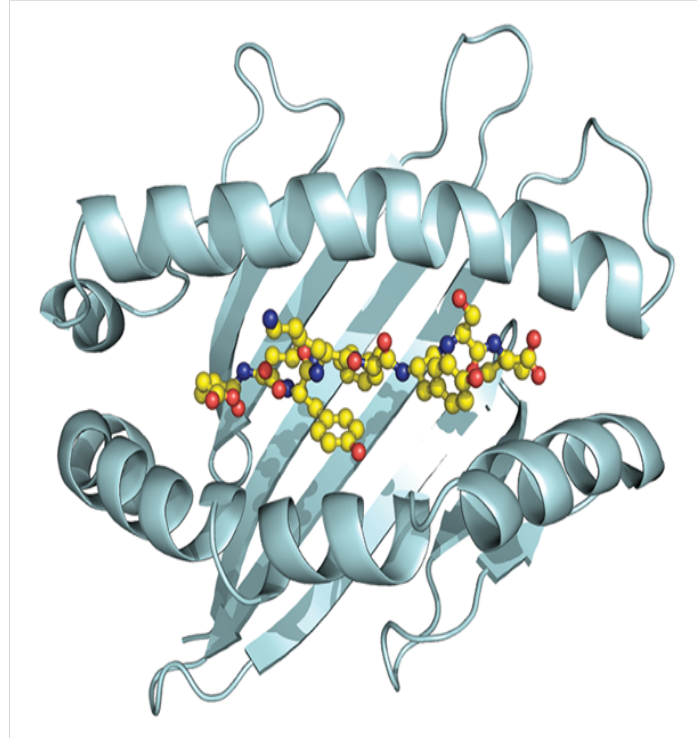
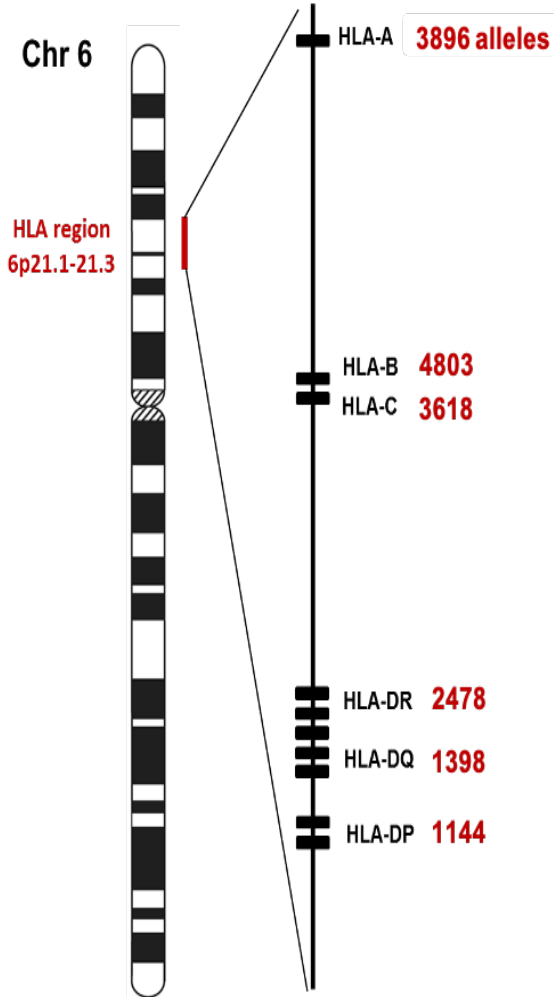


# Does Recognition of Specific SARS CoV2 Peptides Result in Protection?

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**Dr. Mary Carrington**  
**Dr. Stephen Chanock**



**Specimens received: N ~2200**

- **Massachusetts General Hospital**
- **Brigham and Women's Hospital**
- **University of California-San Francisco**
- **Emory University**

**Specimens genotyped: N ~1607**

**HLA loci are highly polymorphic in humans and some allotypes of these genes appear better able to present peptides that elicit a protective immune response.**

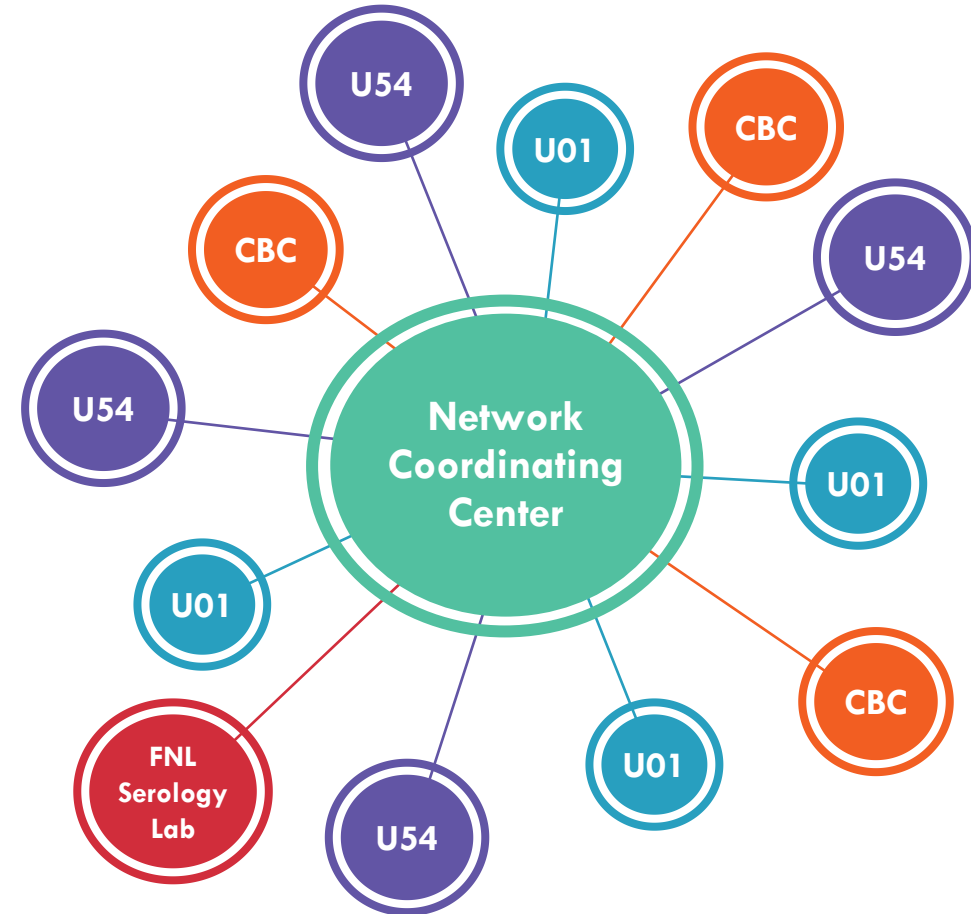


# Serological Sciences Network (SeroNet): A View from Within

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- Designed to be a highly interactive network.
- Sharing of data and resources within SeroNet.
- Open access publication.
- Data and resources made publicly available.



**Dr. Dinah Singer**  
**Dr. Jim Cherry**  
**Dr. Ligia Pinto**  
**Dr. Len Freedman**  
**Dr. Sara Hook**  
**Dr. Doug Lowy**  
**Dr. Ned Sharpless**  
and many others

## Frederick National Laboratory Serology Laboratory

- Implement and qualify SARS-CoV-2 assays.
- Develop qualified assay standards and generate novel reagents.
- Procure and characterize serum samples from SARS-CoV-2 patients and controls and establish serum panels.
- Share assays, reagents, and standards within SeroNet.

**4-8 CBCs:** Serological Sciences Capacity Building Centers (  
**4-8 U54s:** Serological Sciences Centers of Excellence  
**5-10 U01s:** Serological Sciences research projects  
**Frederick National Laboratory Serology Laboratory**  
**Network Coordinating Center Frederick National Laboratory**



# COVID-19 Clinical Trials with NIAID

- **ACTT**: Adaptive COVID-19 Treatment Trial – a Multicenter, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19 in hospitalized patients.
- Four versions; 1-3 completed, 4 enrolling at US and international sites:
  - **ACTT-1**: Remdesivir vs. placebo
  - **ACTT-2**: Remdesivir +/- Baricitinib/placebo
  - **ACTT-3**: Remdesivir +/- Interferon beta 1a/placebo
  - **ACTT-4**: Remdesivir + Dexamethasone/placebo vs. Baricitinib/placebo
- 3,500 subjects enrolled into four Phase 3 studies since February 2020.
- Studies Outcomes are:
  - FDA Emergency Use Authorizations (EUAs) for Remdesivir and Baricitinib
  - FDA approval of Remdesivir for treatment of COVID-19



# COVID-19 Clinical Trials in Concert with NIAID

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**NIAID/DMID and CMRP**

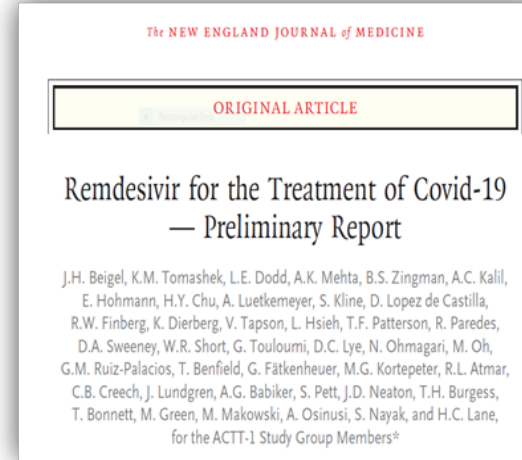
**Beth Baseler  
Laura McNay  
Dr. Barry Gause  
Dr. John Beigel**

## Remdesivir

International placebo-controlled trial of hospitalized COVID-19 patients on ventilators or oxygen-dependent.

60 sites and 1063 cases.

Completed accrual in ~2 months.



**Emergency Use  
Authorization**

**FDA-approved**

## Remdesivir +/- Baricitinib

International double-blind randomized placebo-controlled trial of hospitalized COVID-19 cases on ventilators or oxygen-dependent.

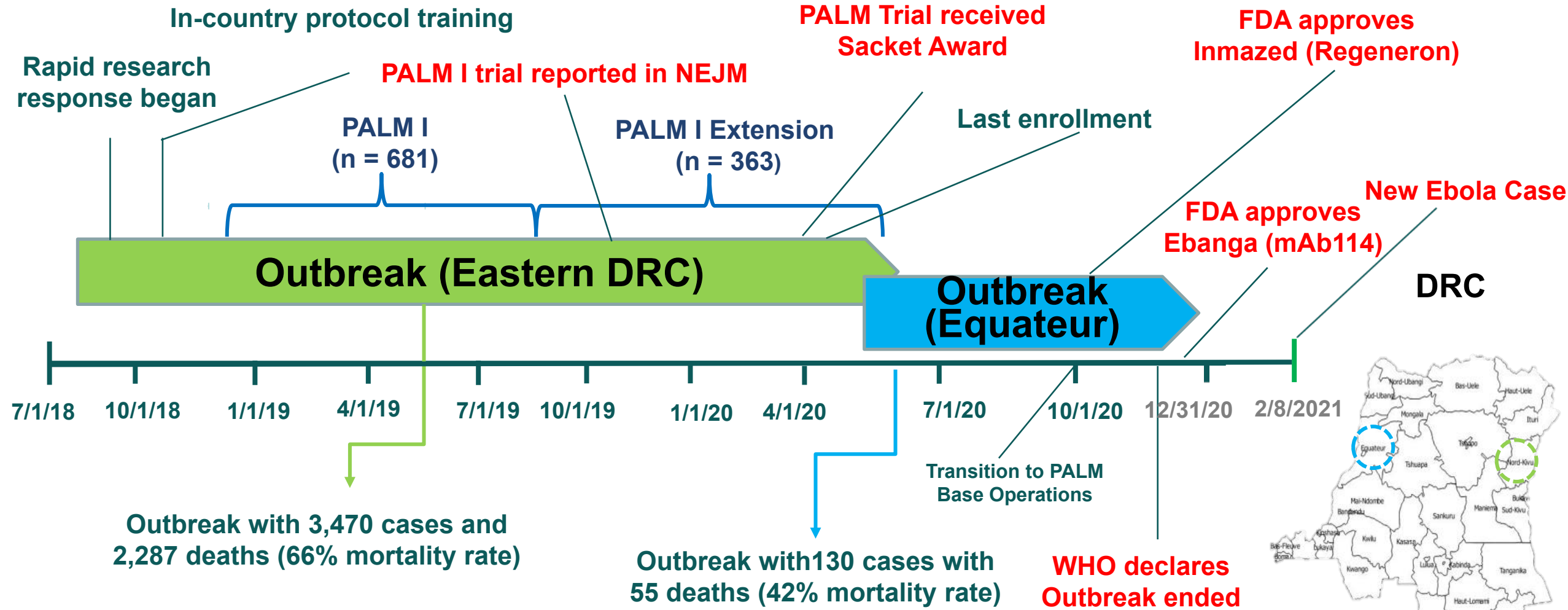
71 sites and 1034 cases.

Completed accrual in ~1.5 months.



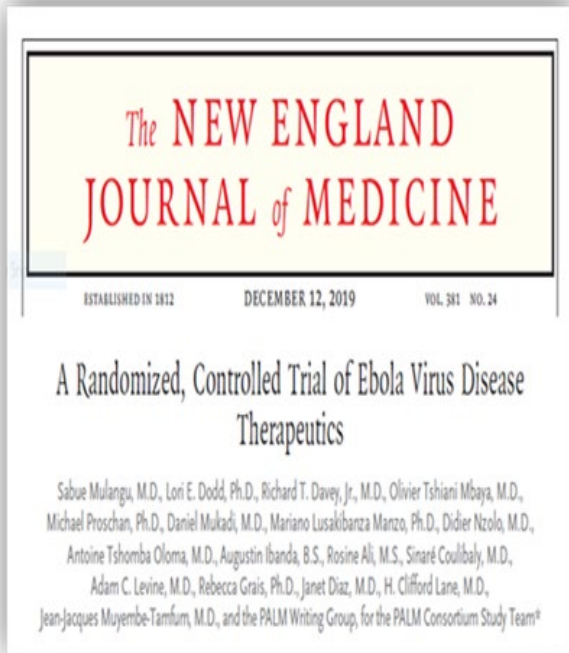
**Emergency Use  
Authorization**

# Democratic Republic of the Congo and Course of the Latest Ebola Virus Outbreaks



# NIAID and Frederick National Laboratory Ebola Trial: A Cycle of Discovery

**PALM  
Consortium**



**PALM  
Consortium**



**Remdesivir**



**ZMapp**



**REGN-EB3  
(Inmazeb)**



**mAb114  
(Ansuvimab  
or Ebanga)**



**Orphan Drug and  
Breakthrough Therapy  
designation  
and European  
Medicines Agency**



**FDA approval  
Regeneron  
October 2020**



**Orphan Drug and  
Breakthrough  
Therapy designation**

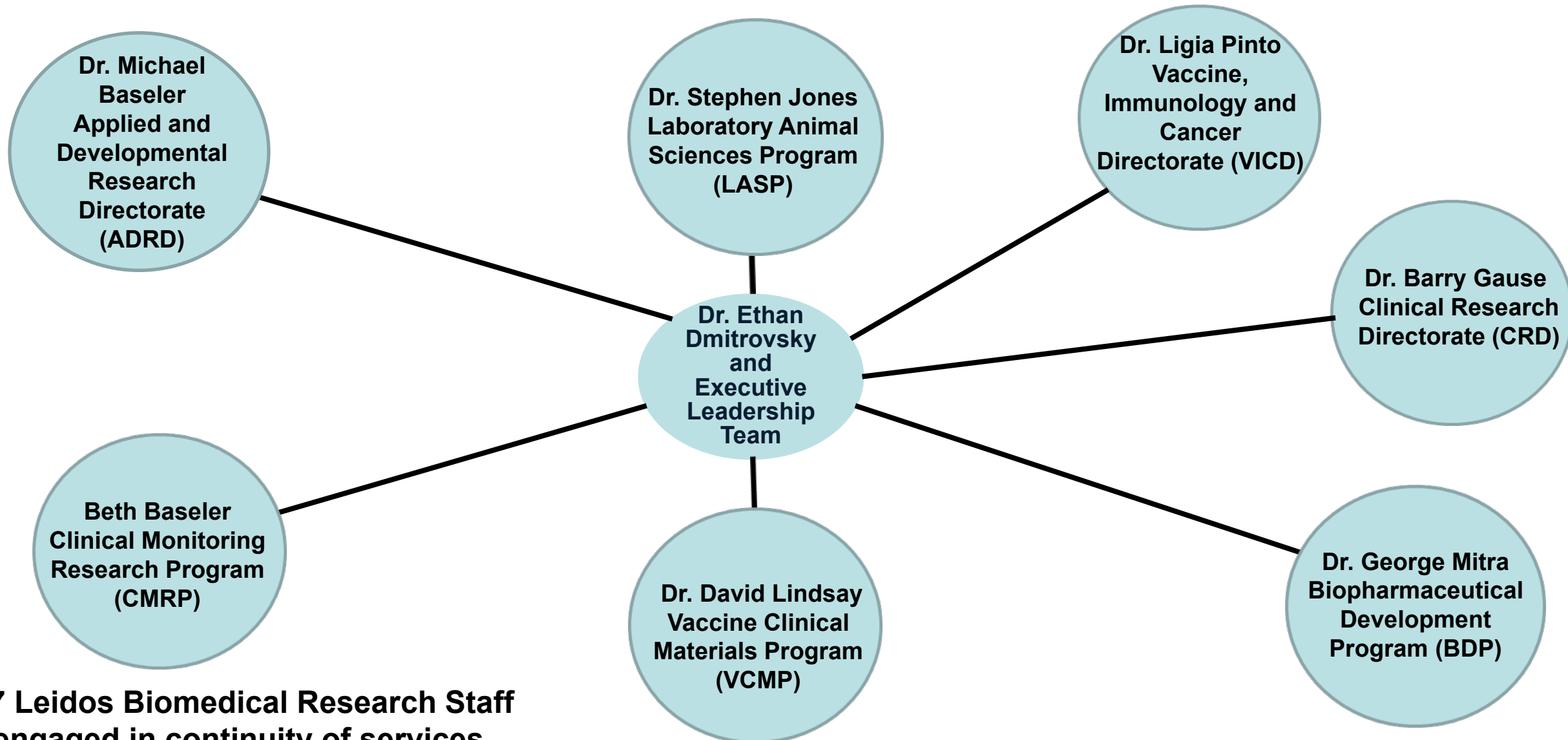


**FDA approval  
Ridgeback  
Biotherapeutic  
December 2020**

**NIAID  
VRC and DCR  
CMRP  
VCMP**



# Continuity of Veterinary and Clinical Services During the Pandemic



**227 Leidos Biomedical Research Staff  
engaged in continuity of services**

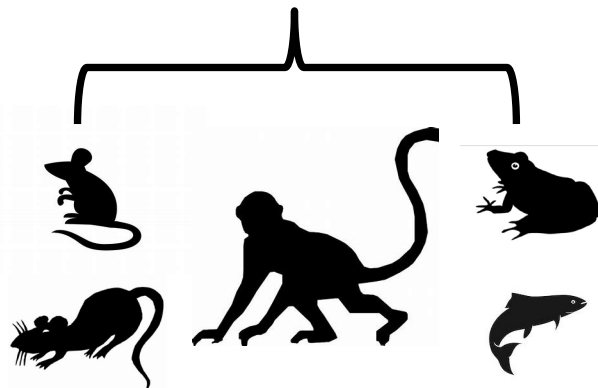


# Case Study: Continuity of Essential Services for Laboratory Animal Sciences

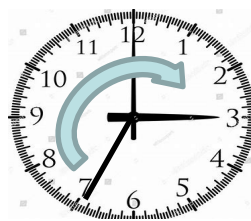
## LASP (pre-pandemic)



NCI vivarium (Bethesda and Frederick)  
essential veterinary and husbandry services



Sun	Mon	Tue	Wed	Thu	Fri	Sat



*standard work schedule*

## LASP (during pandemic)

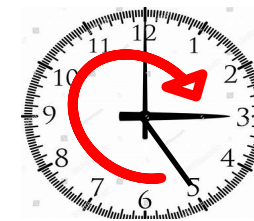


Team A

Team B

Team C

Sun	Mon	Tue	Wed	Thu	Fri	Sat



*split shifts / elongated workday and week*



# Laboratory Animal Sciences Program (LASP)

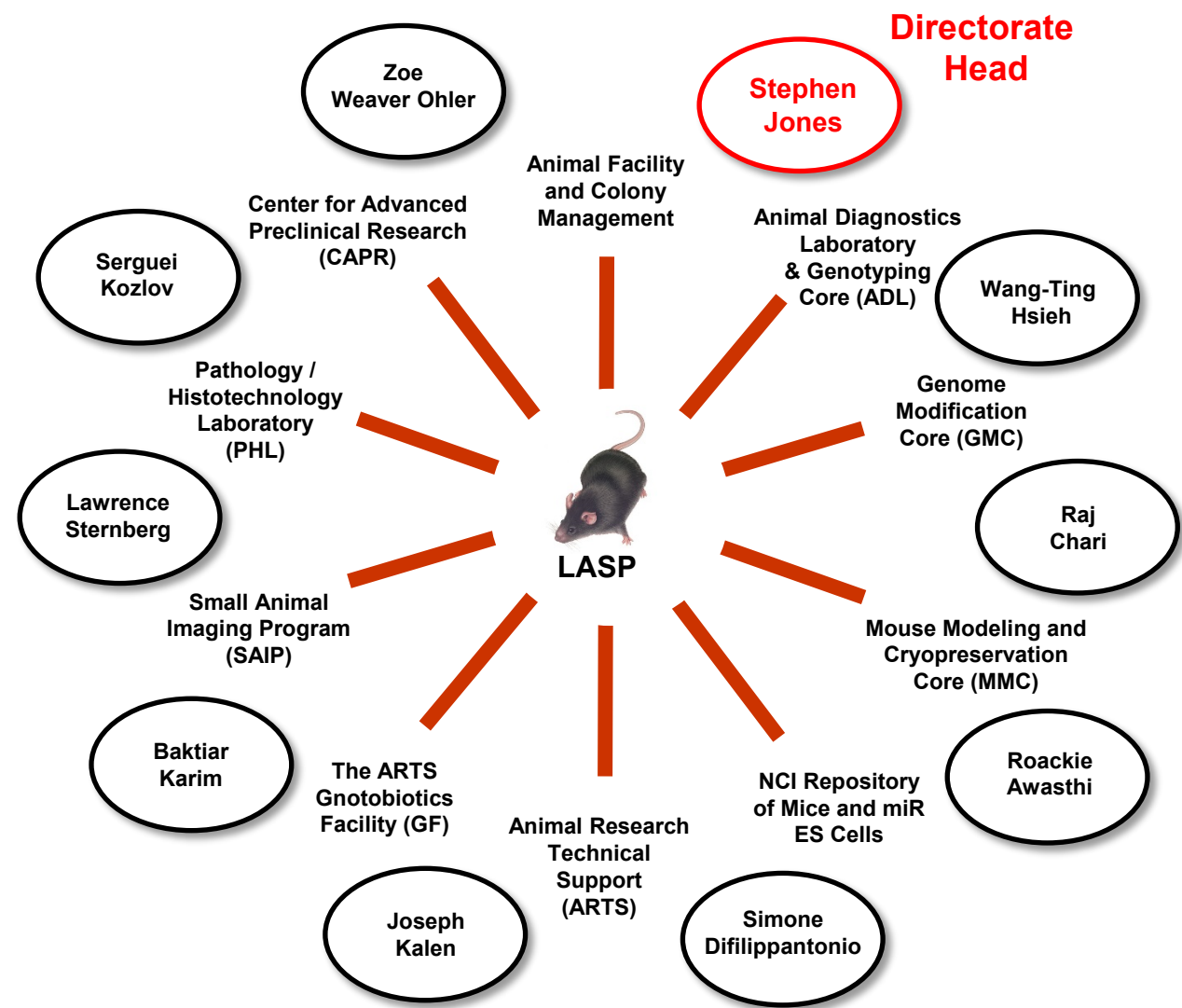
**Funding Source: NCI Office of the Director**

**Supports**

**NCI Intramural**  
**Center for Cancer Research**  
**OD (Animal Health Monitoring)**  
**Division of Cancer Epidemiology and Genetics**  
**NCI Extramural**  
**NCI Division of Cancer Treatment and Diagnosis**  
**Division of Cancer Biology**  
**NIAID, NIAMS, FNLCR**  
**Interagency Agreements**  
**cCRADAs**

**Recent High-Impact Publications**

**Choi et al., Nat Commun, 2020.**  
**Ruiz-Rodado et al. Cancer Metab, 2020.**  
**Buel et al., Nat Commun, 2020.**  
**Chibaya et al. PNAS, 2021.**  
**Torres-Ayuso et al., Cancer Disc, 2021.**  
**Shrestha et al., J Cell Bio, 2021.**



# Support for NCI CAR-T Cell Trials

## With the Division of Cancer Treatment and Diagnosis (DCTD)

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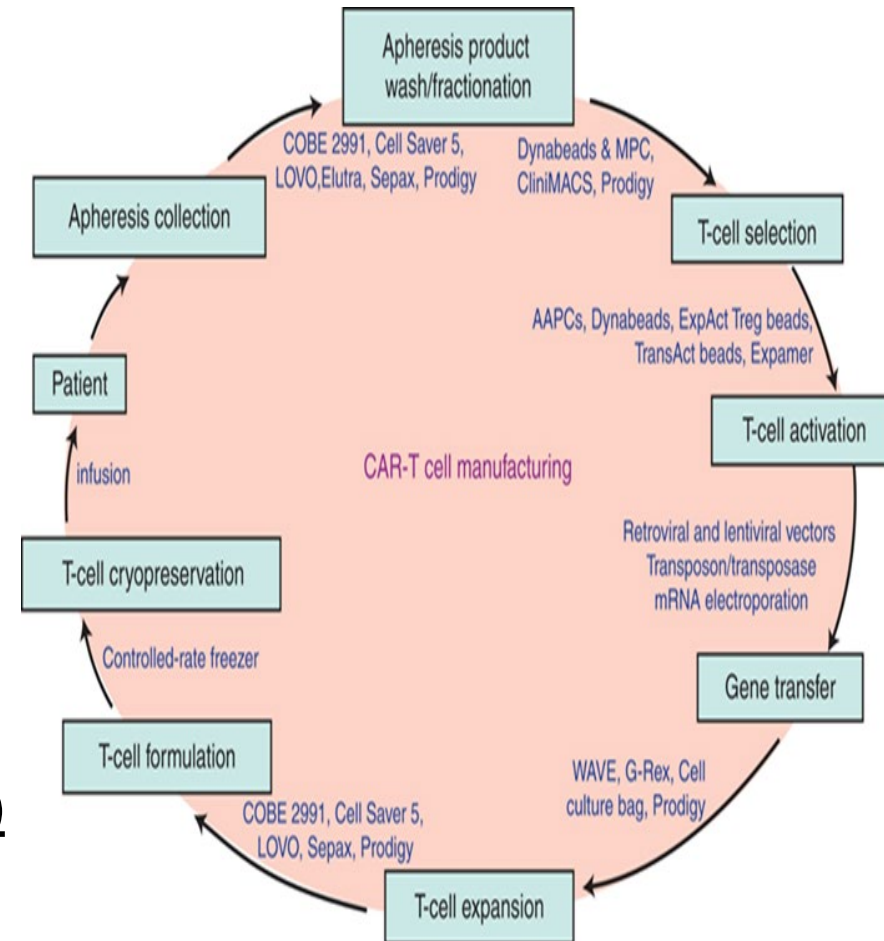
### Clinical Trial Phased Approach

#### Pediatric AML (CD33)

- Manufactured by Biopharmaceutical Development Program (BDP).
- Clinical Trials with National Marrow Donor Program (NMDP).
- Three patients already treated at NIH and one at CHOP.

#### Pediatric Neuroblastoma/Osteosarcoma (GD2)

- Manufacture will be by BDP.
- Clinical Trials are with NMDP.
- Open first at Clinical Center later this year.



**Dr. Ned Sharpless**  
**Dr. James Doroshow**  
**Dr. Anthony Welch**  
**Dr. Jason Yovandich**  
**Dr. Barry Gause**  
**Dr. George Mitra**

### **Prodigy System**

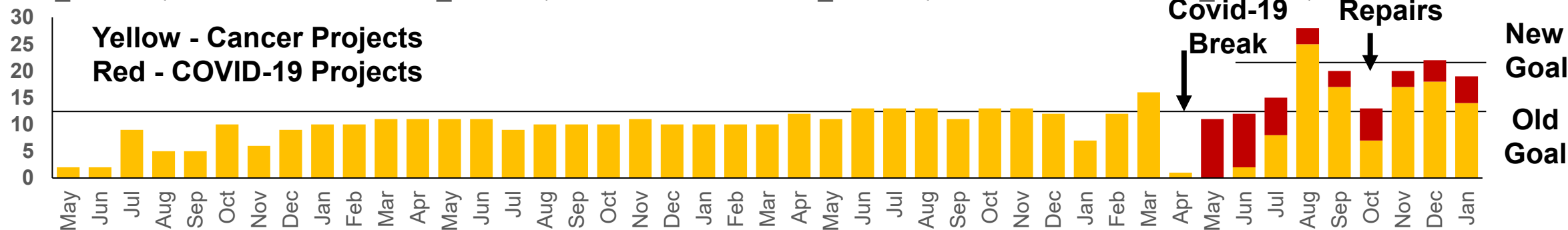
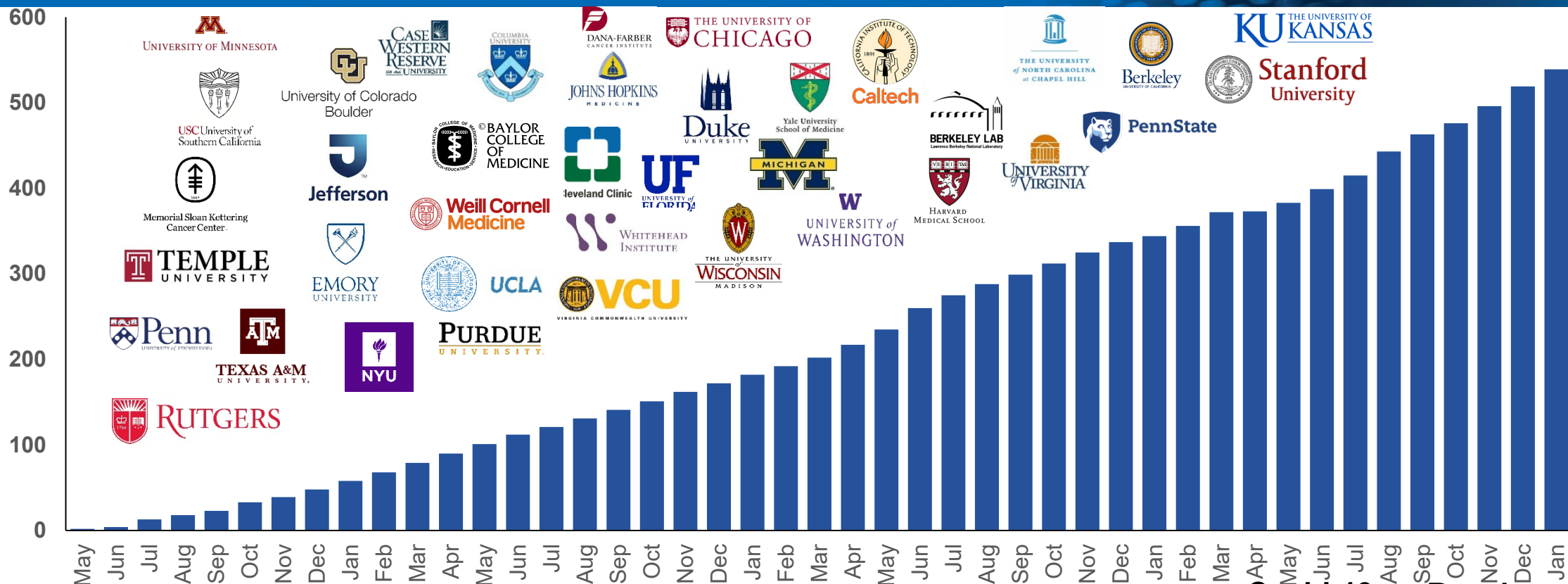


# NCI National Cryo-EM Facility

## The First Four Years

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# Recent Honors and Recognitions

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**Ruth Nussinov, Ph.D.**  
**2020 Fellow**  
**American Physical  
Society**



**Jeffrey Lifson, M.D.**  
**2020 Fellow**  
**American Association for  
the Advancement of  
Science**



**Mary Carrington, Ph.D.**  
**2021 Fellow**  
**American Academy of  
Microbiology**

# Asymptomatic COVID Testing Program

Frederick National Laboratory has five asymptomatic COVID testing clinics sites. These were put in place within weeks and serve all NIH employees and contractors.

Four clinics are at three Frederick locations. One clinic is at NCI Shady Grove.

Over 5,600 tests were conducted to date with a positivity rate of 0.2%.

Location	Tests Completed	Positive Results
Frederick Sites	5017	14
Shady Grove	640	0



# Support for Frederick National Laboratory Staff and Community

## Concierge service:

Child and elder care resources.

## Programs with Johns Hopkins Medicine:

- ***Work Stride*** to help reduce cancer risk and to assist employees who are managing a cancer diagnosis or serving as a caregiver for someone battling cancer while continuing to work.
- ***DECIDE*** and ***Act 2***: Diabetes management and prevention programs.
- ***HealthyWorks*** portal for access to healthy living and disease prevention information.
- ***Balance***: a behavioral health resource to improve health and overall well-being.

## Community service:

“Nourish our Neighbors”



# Frederick National Laboratory Academic Partnerships

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- Appointment and exchange of scientific staff
- Sabbatical opportunities
- Student training
- Postdoctoral fellowships
- Student internships
- Scientific projects





# Conclusions

- **Reviewed Frederick National Laboratory's rapid response to this pandemic that threatened the public's health.**
- **Despite this pivot other essential work continued.**
- **This did not prevent decisive discovery, quantitative biology, translational and clinical science.**
- **Our public-private partnership is expected for a Federally Funded Research and Development Center.**

# Acknowledgements

**We thank our NCI, NIAID, and NIH colleagues along with the Key Staff, Directorate Heads and their teams for service during the pandemic.**

**Dr. Kathy Terlesky, Chief Operating Officer  
Dr. Leonard Freedman, Chief Science Officer  
Dr. Barry Gause, Chief Medical Officer  
Beth Baseler, Clinical Monitoring Research Program  
Dr. Michael Baseler, MS, Applied and Developmental Research  
Frank Blanchard, Public Affairs and Communications  
Terri Bray, Environment, Health and Safety  
Sue Bruce, MBA, Financial Operations  
Dr. Mary Carrington, Basic Science Program  
Dr. Bernard Courtney, Project Management Operations  
Beverly Hayes, Contracts and Acquisitions  
Dr. Claudia Haywood, Esq., Intellectual Property and Strategic Agreements  
Shannon Jackson, Chief Ethics and Compliance Officer  
Dr. Jeffrey Lifson, AIDS and Cancer Virus Program**

**Dr. Stephen Jones, Laboratory Animal Sciences Program  
Dr. David Lindsay, Vaccine Clinical Materials Program  
Chris March, Human Resources  
Dr. George Mitra, Biopharmaceutical Development Program  
Dr. Dwight Nissley, Cancer Research Technology Program  
Rich Pendleton, Business Service  
Dr. Ligia Pinto, Vaccine, Immunology and Cancer  
Dr. Vladimir Popov, Partnership Development Office  
Brett Smith, Business Enterprise Systems  
Dr. Eric Stahlberg, Biomedical Informatics and Data Science  
Dr. Dante Tedaldi, Facilities Maintenance and Engineering**