

Frederick National Laboratory Operations During the Pandemic

Frederick National Laboratory
for Cancer Research

sponsored by the National Cancer Institute



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American Cancer Society Professor
President, Leidos Biomedical Research and 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 Frederick National Laboratory's response during the pandemic and how operational support was provided to NCI, NIAID and other critical programs.**
- **As a Federally-Funded Research and Development Center (FFRDC) our mandate is rapid public health response. Examples are cited.**
- **Describe the Emergency Operations Center and how vital functions were sustained even as we look ahead to future work.**
- **Answer your questions.**

Frederick National Laboratory Responsibilities During an Emergency

During an emergency, Frederick National Laboratory has this contractual responsibility:

”The Contractor shall maintain an emergency management program that encompasses laboratory activities and infrastructure, to include emergency planning, preparedness, response and readiness, assurance procedures, elements of which inform the Continuity of Operations Program (COOP).”

We have two operational missions: (1) Maintain minimal essential services and (2) Continue without disruption vital clinical, animal husbandry and laboratory services supporting the clinical enterprise.

Contractual Responsibility: Continuity of Operations and the Emergency Operations Center

Continuity of Operations (COOP)

Objective is to keep mission-critical functions operating despite any situation.

Emergency Operations Center (EOC)

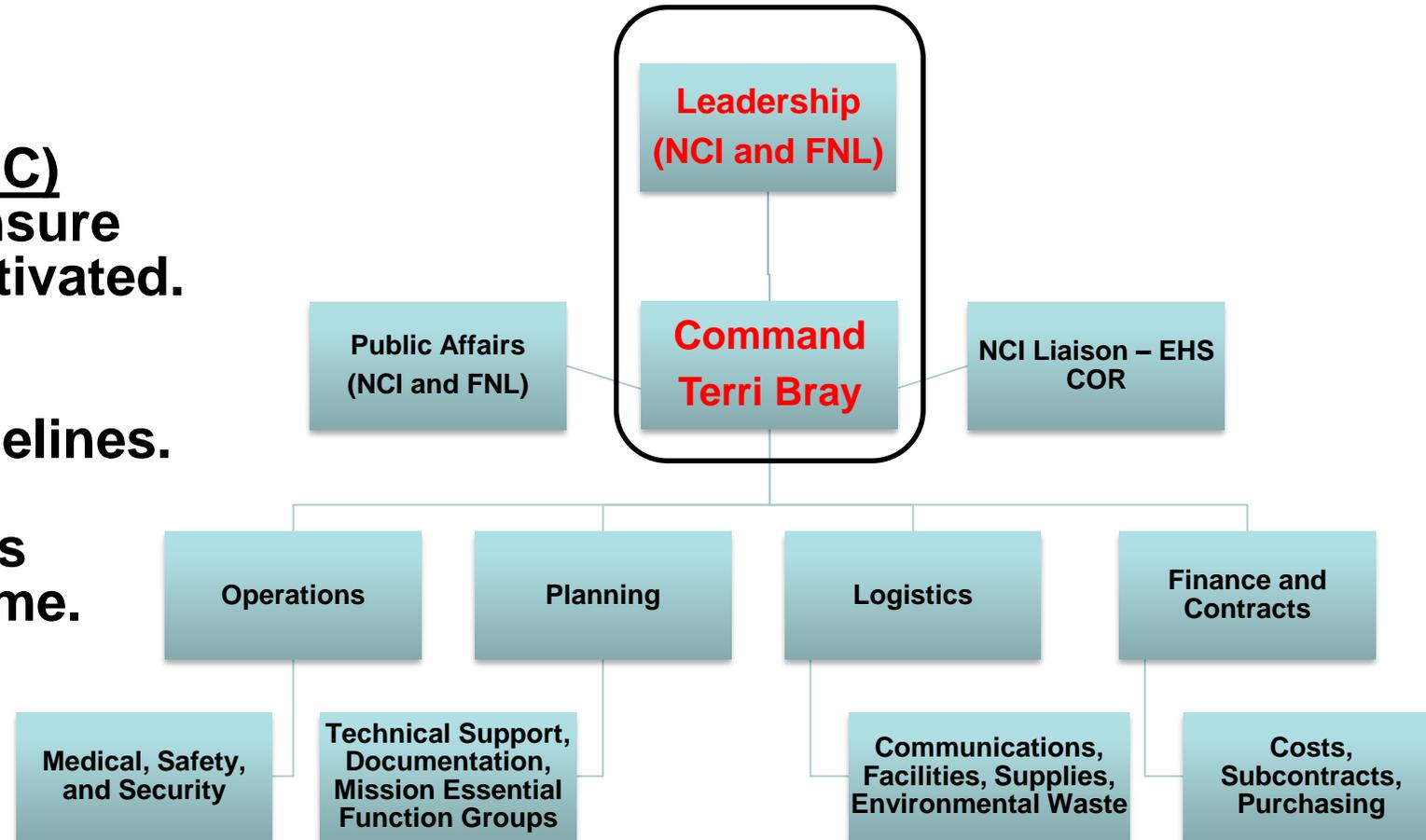
Provides structure and focus to ensure minimal essential functions are activated.

EOC is based on FEMA's National Incident Management System guidelines.

This was the first time the EOC was activated for a full and extended time.

Assess lessons learned.

Collaboration, communication and rapid response.



Frederick National Laboratory Operational Response to the Pandemic

Support of Operations

- Finance, Project Management and Contracts staff teleworking and delivered Task Order proposals.
- Enhanced communications with program staff via weekly teleconferences.
- Initially, biweekly Executive Leadership Team meetings.

Personnel

- Operations and Maintenance staff prioritized mission critical and safety areas (staff at 50% of levels).
- Logistics, warehouse, and travel staff used Discretionary Leave (no financial effect on government).

Frederick National Laboratory Clinical and Scientific Response to the Pandemic

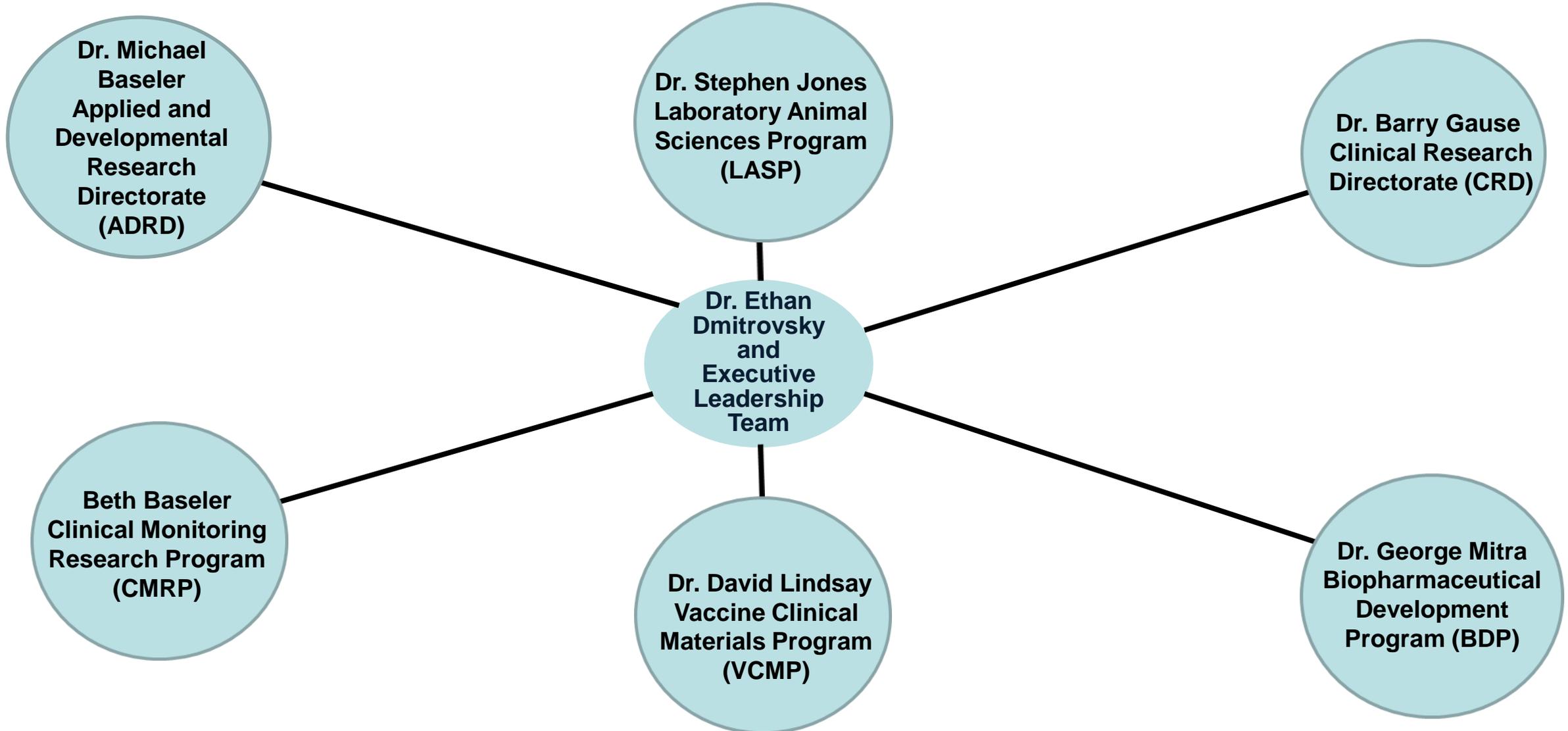
Support of Personnel and Facility

- Activated the Emergency Operations Center.
- Deployed laptops with VPN accounts for teleworking.
- Established 60+ Microsoft Teams to optimize teleworking.
- Configured remote “jump” boxes for scientific team telework.
- Developed custodial strike teams.

Support of Clinical Care and Science

- Prioritized Institutional Biosafety Committee work on COVID-19.
- Excess and aging N-95 respirators distributed.
- Focus clinical laboratory on support of COVID-19 efforts.
- Pilot Plant produced hand sanitizers.

Continuity of Veterinary and Clinical Services During the Pandemic



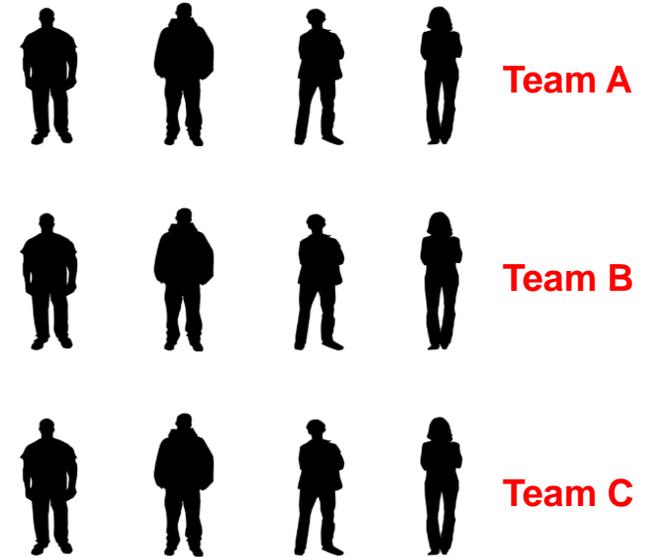
Case Study: Continuity of Essential Services for Laboratory Animal Sciences

LASP (pre-pandemic)



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

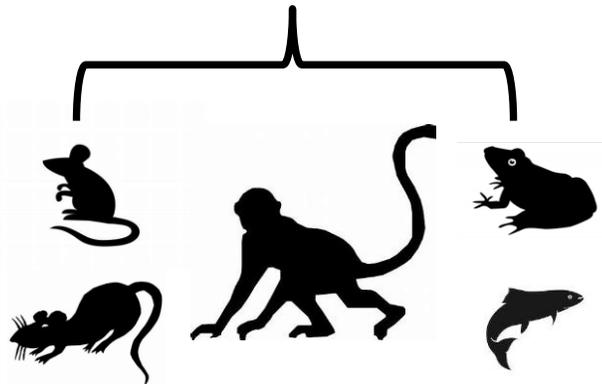
LASP (during pandemic)



Sun	Mon	Tue	Wed	Thu	Fri	Sat



standard work schedule

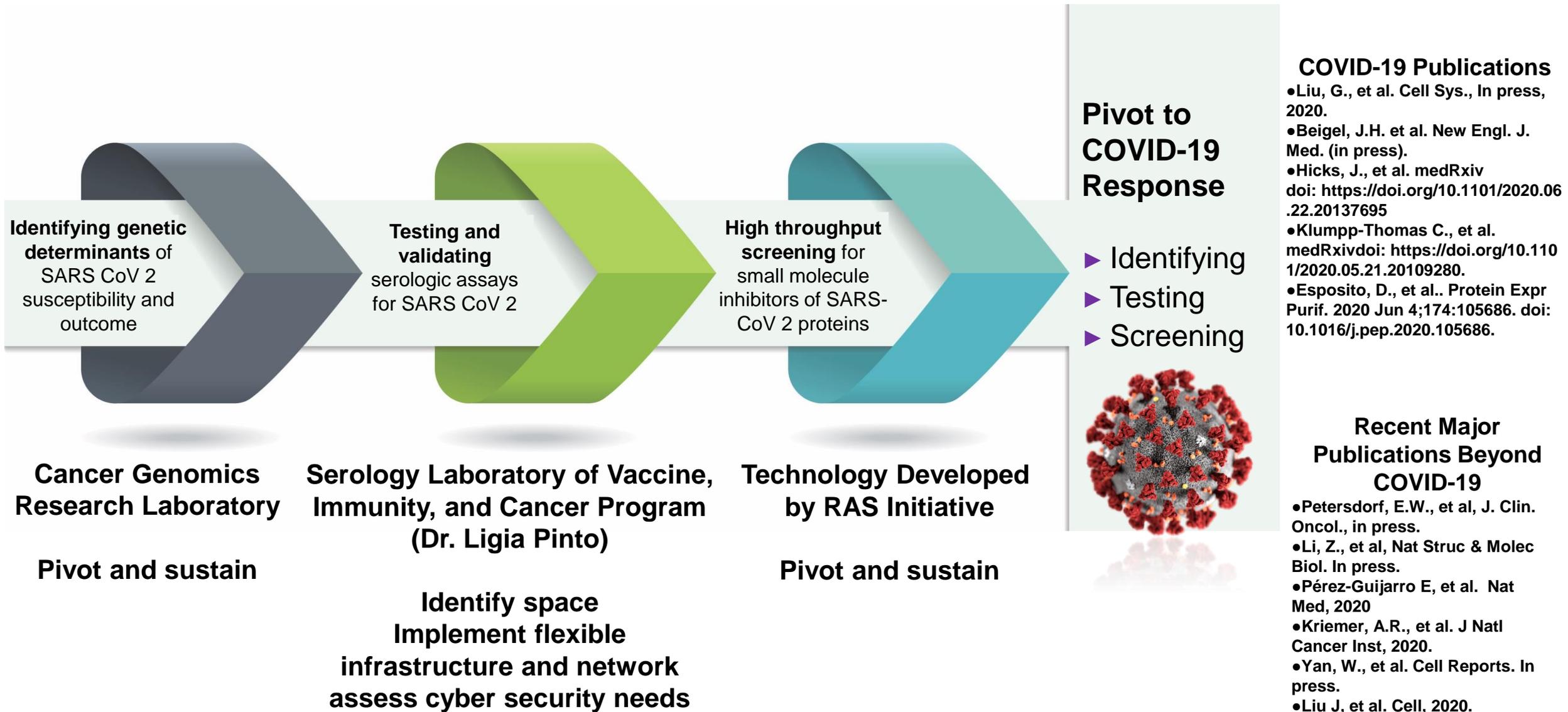


Sun	Mon	Tue	Wed	Thu	Fri	Sat



split shifts / elongated workweek

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



Collaborations between National Institute of Allergy and Infectious Diseases and Frederick National Laboratory

Frederick
National
Laboratory
for Cancer Research

sponsored by the
National Cancer Institute

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Remdesivir for the Treatment of Covid-19 — Preliminary Report

J.H. Beigel, K.M. Tomashek, L.E. Dodd, A.K. Mehta, B.S. Zingman, A.C. Kalil, E. Hohmann, H.Y. Chu, A. Luetkemeyer, S. Kline, D. Lopez de Castilla, R.W. Finberg, K. Dierberg, V. Tapson, L. Hsieh, T.F. Patterson, R. Paredes, D.A. Sweeney, W.R. Short, G. Touloumi, D.C. Lye, N. Ohmagari, M. Oh, G.M. Ruiz-Palacios, T. Benfield, G. Fätkenheuer, M.G. Kortepeter, R.L. Atmar, C.B. Creech, J. Lundgren, A.G. Babiker, S. Pett, J.D. Neaton, T.H. Burgess, T. Bonnett, M. Green, M. Makowski, A. Osinusi, S. Nayak, and H.C. Lane, for the ACTT-1 Study Group Members*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Randomized, Controlled Trial of ZMapp for Ebola Virus Infection

The PREVAIL II Writing Group, for the Multi-National PREVAIL II Study Team*

The NEW ENGLAND
JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 12, 2019 VOL. 381 NO. 24

A Randomized, Controlled Trial of Ebola Virus Disease Therapeutics

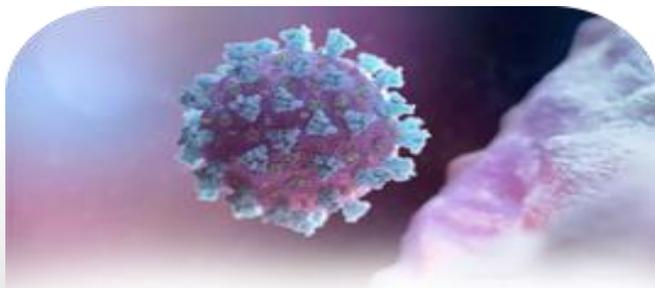
Sabue Mulangu, M.D., Lori E. Dodd, Ph.D., Richard T. Davey, Jr., M.D., Olivier Tshiani Mbaye, M.D., Michael Proschan, Ph.D., Daniel Mukadi, M.D., Mariano Lusakibanza Manzo, Ph.D., Didier Nzolo, M.D., Antoine Tshomba Oloma, M.D., Augustin Ibanda, B.S., Rosine Ali, M.S., Sinaré Coulibaly, M.D., Adam C. Levine, M.D., Rebecca Grais, Ph.D., Janet Diaz, M.D., H. Clifford Lane, M.D., Jean-Jacques Muyembe-Tamfum, M.D., and the PALM Writing Group, for the PALM Consortium Study Team*

Science | AAAS

VACCINES

Rapid development of a DNA vaccine for Zika virus

Kimberly A. Dowd,^{1*} Sung-Youl Ko,^{2*} Kaitlyn M. Morabito,² Eun Sung Yang,² Rebecca S. Pelc,¹ Christina R. DeMaso,¹ Leda R. Castilho,^{2,3} Peter Abbink,⁴ Michael Boyd,⁵ Ramya Nityanandam,⁴ David N. Gordon,¹ John Robert Gallagher,⁵ Xuejun Chen,² John-Paul Todd,² Yaroslav Tsybovsky,⁶ Audrey Harris,⁵ Yan-Jang S. Huang,⁷ Stephen Higgs,⁷ Dana L. Vanlandingham,⁷ Hanne Andersen,⁸ Mark G. Lewis,⁸ Rafael De La Barrera,⁹ Kenneth H. Eckels,⁹ Richard G. Jarman,¹⁰ Martha C. Nason,¹¹ Dan H. Barouch,⁴ Mario Roederer,² Wing-Pui Kong,² John R. Mascola,² Theodore C. Pierson,^{1†} Barney S. Graham^{2†}



Support of the international multi-center placebo-controlled randomized remdesivir trial in high risk COVID-19 patients (those who are hospitalized and oxygen-dependent or on a ventilator).



Support of Ebola relief efforts and the four-arm trial in the Democratic Republic of Congo (including production of one of the successful agents) leading to fast-track status by the FDA.

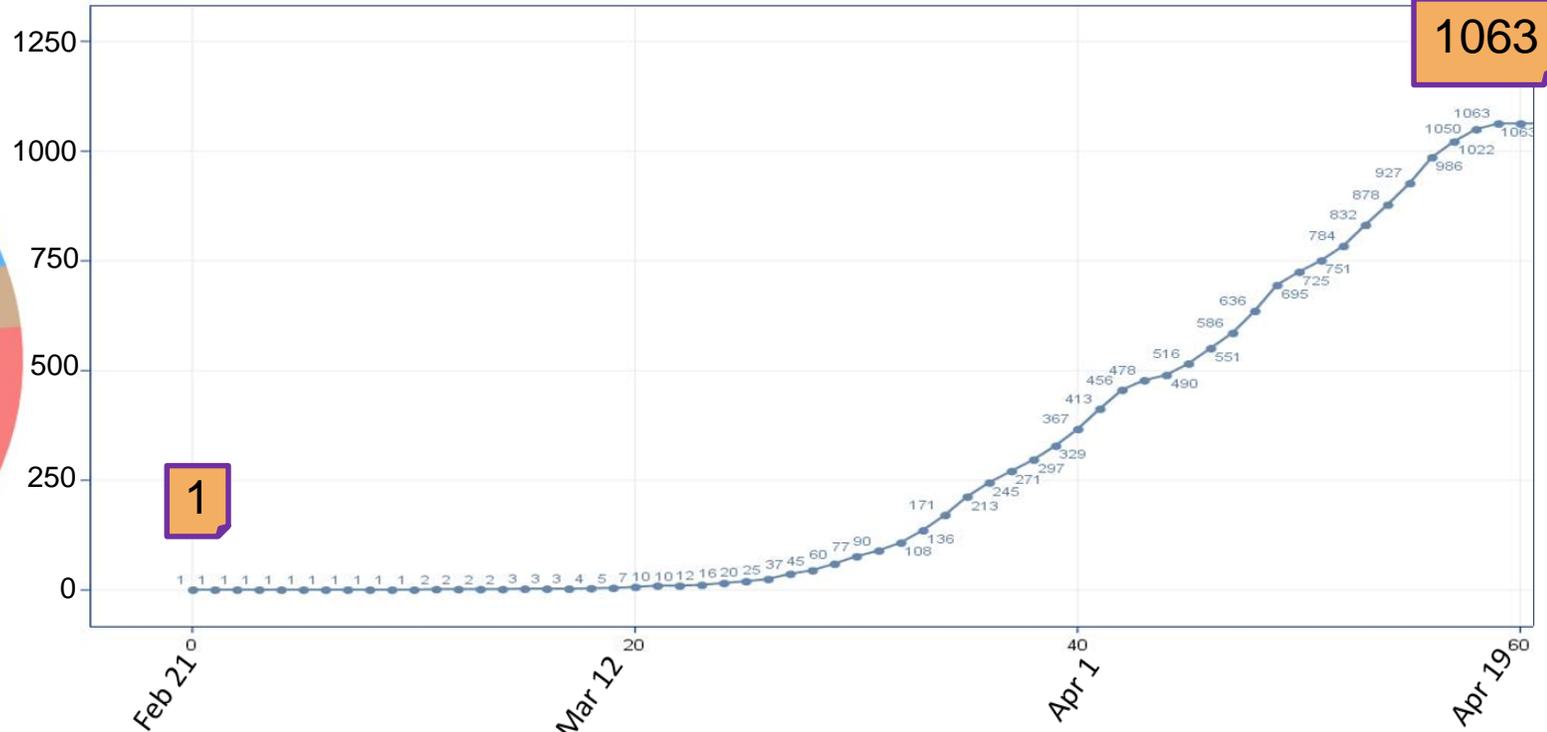
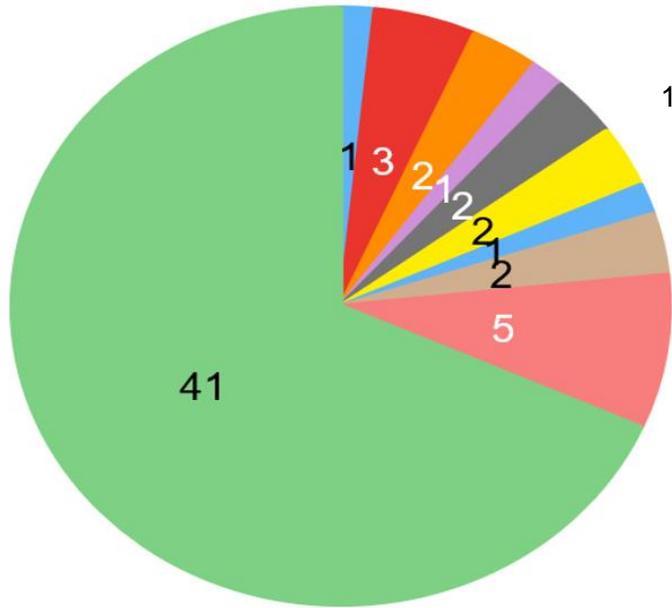


Conduct of the international Zika trial (including production of the vaccine).

NIAID COVID-19 Trials and Frederick National Laboratory

An International Multi-Center Randomized Placebo Controlled Trial of Remdesivir.

- Denmark
- Germany
- Greece
- Japan
- Korea
- Mexico
- Singapore
- Spain
- United Kingdom
- United States



ACTT-1 Enrollment

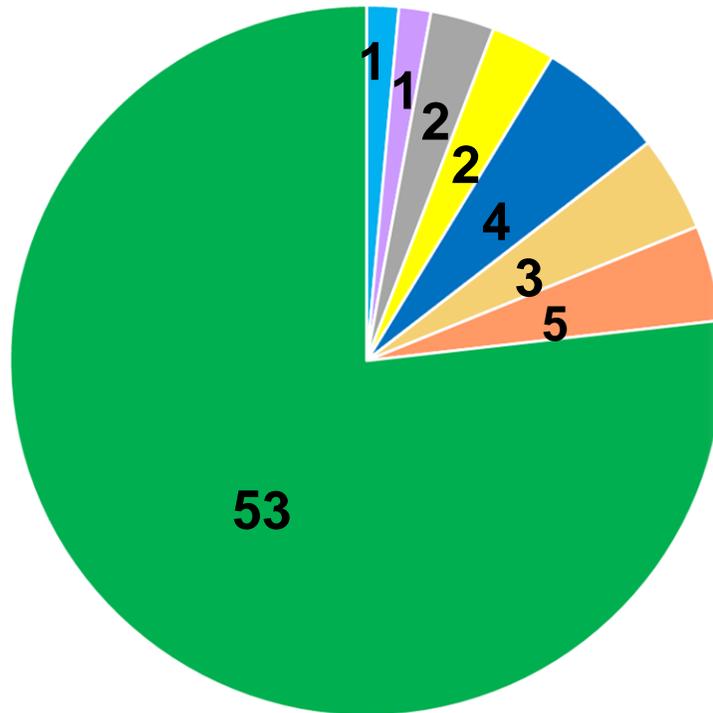
N=60
Main Sites

Those hospitalized with COVID-19 with lower respiratory tract disease (radiographic infiltrate, oxygen requirement, or mechanical ventilator).

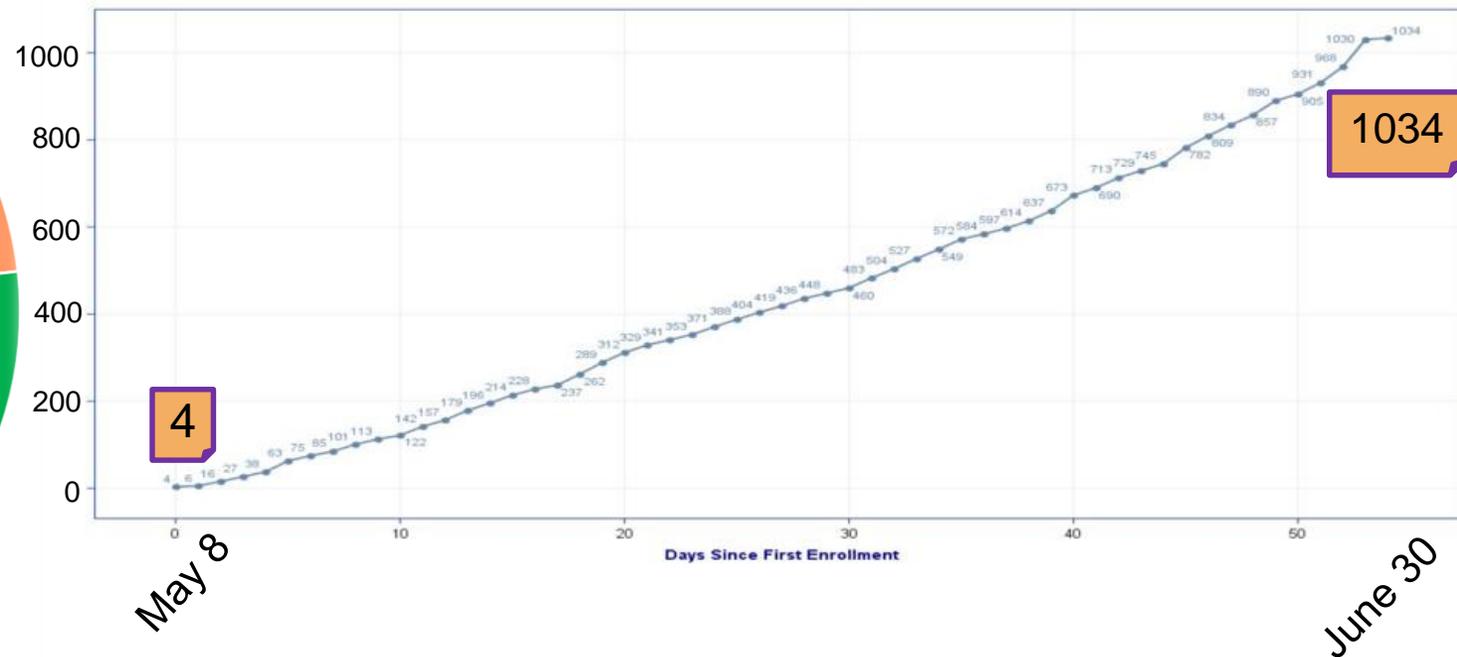
NIAID DMID COVID-19 ACTT-2 Trial and Frederick National Laboratory

International Multi-Center Randomized Placebo Controlled trial of Remdesivir +/- Baricitinib.

- Denmark
- Japan
- Korea
- Mexico
- Singapore
- Spain
- United Kingdom
- United States



N=71
Main Sites



ACTT-2 Enrollment

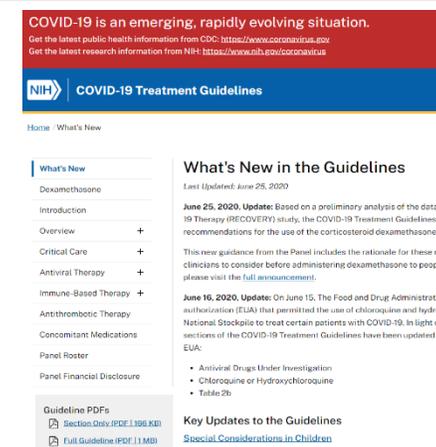
Trial Closed 6/30/2020

COVID-19 Treatment Guidelines Website

- Partnership with HHS, NIH, NIAID, FNL and subcontractor to develop and manage public-facing NIH COVID-19 treatment guidelines website.
- Dissemination of updates and changes to NIH treatment guidance.
- Facilitation of NIH information security certification and accreditation for National Institute of Standards and Technology moderate classification.
- Establishment of communication modes (Twitter, GovDelivery) and downloadable reference materials.

Date	Users		Sessions	Pageviews
	US	International		
Week 1 (4/21 – 4/27)	161,547	118,030	360,669	1,184,572
Week 2 (4/28 – 5/4)	43,892	26,928	89,145	278,947
Week 3 (5/5 – 5/11)	27,525	18,019	56,692	177,032
Week 4 (5/12 – 5/18)	27,024	22,057	60,884	151,770
Week 5 (5/19 – 5/25)	21,090	21,050	51,340	121,498
Week 6 (5/26 – 6/1)	23,798	18,826	50,949	115,213
Week 7 (6/2 – 6/8)	12,275	16,875	35,974	83,429
Week 8 (6/9 – 6/15)	17,568	21,957	48,180	108,641
Week 9 (6/16 – 6/22)	15,952	20,586	44,321	101,166
Week 10 (6/23-6/29)	28,195	28,128	68,094	140,008
Week 11	6/30	7,710	5,788	14,906
	7/1	6,043	6,396	13,554
Week 11 Subtotal		13,753	12,184	28,460
Total		378,866	312,456	866,248

Users – the number of new and returning people who visit the site
Sessions – a visit to the website. Note that if a person returns within a 30-minute timeframe, it will still count as one session. If they return after 30 minutes, it will count as a new session.
Pageviews – total instances of any page on the website being loaded (or reloaded) in a browser



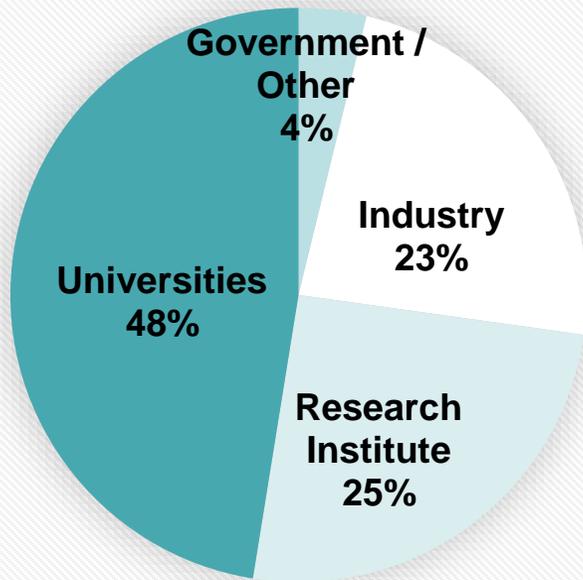
Overview of Website Activity 4/21/20 - 7/1/20

External Partnerships and Contractor Responsibilities

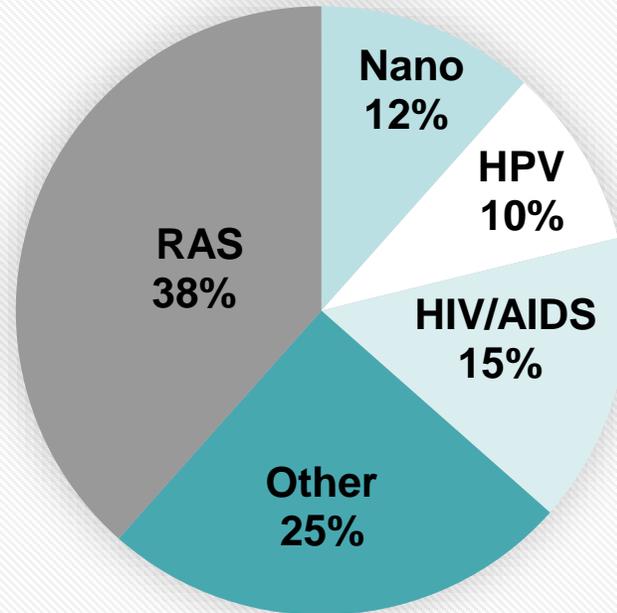
- **“The Contractor maintains relationships with the broader research community to enhance the intellectual vitality and research relevance of the Laboratory.”**
- **“The Contractor actively develops and pursues collaborative engagement with public and private partners... with the goals of discovery, innovation and improvement of human health. The Contractor is to work with civic, academic and private organizations to advance biomedical research, scientific discovery, and the mission of the Frederick National Laboratory.”**

Partnerships at the Frederick National Laboratory for Cancer Research

cCRADA, mcCRADA, MOU,
and TSA Partners



cCRADAs by Research Area



- **159 unique partners**
- **53 executed cCRADAs**

Partnering Since March, 2020

- **4 new cCRADAs**
- **14 technical service orders**
- **1 new research collaboration**
- **Added a new service to the Technical Services Program**
- **Participated in the Bio Digital International Convention, meeting with ~90 organizations**
- **Organized a virtual Biotech Connector event (>100 participants)**
- **Held a partnership informational webinar with nearly 200 participants**

Recent Frederick National Laboratory Collaborations with Extramural Community

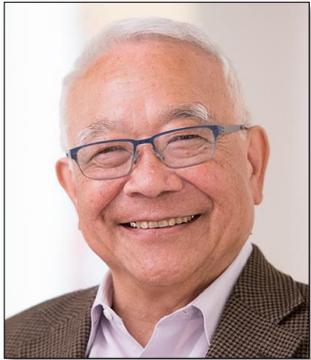
New Partnerships

- HPV Serology Laboratory led by Dr. Ligia Pinto is partnering with the London School of Hygiene and Tropical Medicine School and Gates Foundation to investigate immune responses to HPV vaccine in Tanzania.
- HPV Serology Laboratory evaluates participants' immune response by determining HPV-16/18-specific antibody levels in blood and its avidity.
- The AIDS and Cancer Virus Program led by Dr. Jeff Lifson is collaborating with Beth Israel Deaconess Medical Center and the Gates Foundation to identify potential viral reservoir biomarkers in SIV-infected macaques.
- This study is a multi-center funded collaborative project through the Gates Foundation to understand how HIV persists despite antiretroviral therapy and how it reignites systemic infection when therapy stops.

Recent Educational Initiatives

Hood College with Leidos Biomedical Research held first meeting in 2019: “Imaging Science and Cancer Biology”

Next Meeting: “Artificial Intelligence in Cancer Research and Clinical Care: Turning Promise into Reality” April 27-29, 2021.



**Keynote
Speakers**

Dr. Keith Yamamoto
Executive Vice Chancellor for
Research, UCSF

Advisory Committee:
Ethan Dmitrovsky (FNLCR)
Len Freedman (FNLCR)
Eric Stahlberg (FNLCR)
Peter Choyke (NCI)
Jonas De Almeida (NCI)
Amber Simpson (Queens Univ.)
Marti Head (ORNL)
Warren Kibbe (Duke)
Daniel Rubin (Stanford)
Kristin Swanson (Mayo)



Dr. Maurizio Vecchione
Executive Vice President,
Global Good Research

Organizing Committee:
Len Freedman (FNLCR)
Eric Stahlberg (FNLCR)
Monica Slate (FNLCR)
Debbie Ricker (Hood College)
Lovetta Corson-Morgan (Hood
College)

Frederick National Laboratory and National Cancer Institute Cancer Survivorship Seminar

- Connects our scientists with cancer survivors.
- Our first guest was Mr. Dewey Stringer.
- Hosted by Drs. Hook and Dmitrovsky in February.



ATOM Update and Status Report

Leadership Updates

- **ATOM advisory board formed to broaden engagement and assist leadership.**
- **Dr. Freedman joins Governing Board; Dr. Stahlberg assumes ATOM co-lead.**
- **Three National Laboratories join ATOM (Argonne, Oak Ridge, and Brookhaven).**

Path to Sustainability

- **ATOM strategy prioritizes open data and open models.**
- **Consortium meeting with legal counsel to consider 501c3.**

Broadened Reach

- **ATOM virtually hosting pharmacy interns.**
- **Four manuscripts already accepted or published.**
- **Workflow publicly available on GitHub; Algorithms released.**

Administrative Support of Frederick National Laboratory During Pandemic

FFRDC Contract Portfolio

Task Order Portfolio

- **5 Operational Task Orders - Benefits of services are recurring with annual funded appropriations.**
 - **NCI Task Order also provides the infrastructure supporting NCI-Frederick**
 - **3 NIAID Task Orders supporting different NIAID Divisions**
 - **1 Lease Task Order**
- **84 Non-operational Task Orders**
 - **72 in Scientific or Clinical Groups**
 - **12 Facility Refurbishment Task Orders**
- **5 Supplemental Funding Task Orders (Moonshot or COVID-19)**

Conclusions

- **Cited Frederick National Laboratory's rapid response to this threat to the public's health (administrative and scientific).**
- **Discussed how the National Laboratory pivoted to combat the pandemic while assuring continuity of essential services.**
- **Described strategies to position ourselves for current and future success.**
- **Emphasized partnerships with the cancer science and cancer care community to serve the public's health.**

Acknowledgements

We thank our NCI, NIAID, and NIH colleagues as well as these Key Staff, Directorate Heads and their teams for their 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. 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