Frederick National Laboratory Operations During the Pandemic

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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.
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.
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.
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).
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

Dr. Ethan Dmitrovsky and Executive Leadership Team

Dr. Barry Gause Clinical Research Directorate (CRD)

Dr. Stephen Jones Laboratory Animal Sciences Program (LASP)

Dr. David Lindsay Vaccine Clinical Materials Program (VCMP)

Dr. Michael Baseler Applied and Developmental Research Directorate (ADRD)

Beth Baseler Clinical Monitoring Research Program (CMRP)

Dr. George Mitra Biopharmaceutical Development Program (BDP)
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)**

- Standard work schedule
- Split shifts / elongated workweek

- Team A
- Team B
- Team C
Frederick National Laboratory Pivot with National Cancer Institute to Combat COVID-19

Identifying genetic determinants of SARS CoV 2 susceptibility and outcome

Testing and validating serologic assays for SARS CoV 2

High throughput screening for small molecule inhibitors of SARS-CoV 2 proteins

COVID-19 Publications
- Hicks, J., et al. medRxiv doi: https://doi.org/10.1101/2020.06.22.20137695

Recent Major Publications Beyond COVID-19
Collaborations between National Institute of Allergy and Infectious Diseases and Frederick National Laboratory

**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

N=60
Main Sites

ACTT-1 Enrollment

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.

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.

### Overview of Website Activity

<table>
<thead>
<tr>
<th>Date</th>
<th>Users</th>
<th>Sessions</th>
<th>Pageviews</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1 (4/21 – 4/27)</td>
<td>161,547</td>
<td>360,669</td>
<td>1,184,572</td>
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<td>Week 2 (4/28 – 5/4)</td>
<td>43,892</td>
<td>89,145</td>
<td>278,947</td>
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<td>Week 3 (5/5 – 5/11)</td>
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<td>56,692</td>
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<td>Week 4 (5/12 – 5/18)</td>
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<td>60,884</td>
<td>151,770</td>
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<td>Week 5 (5/19 – 5/25)</td>
<td>21,090</td>
<td>51,340</td>
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<td>Week 6 (5/26 – 6/1)</td>
<td>23,798</td>
<td>50,949</td>
<td>115,213</td>
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<td>Week 7 (6/2 – 6/8)</td>
<td>12,275</td>
<td>35,974</td>
<td>83,429</td>
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<td>Week 8 (6/9 – 6/15)</td>
<td>17,568</td>
<td>48,180</td>
<td>108,641</td>
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<td>Week 9 (6/16 – 6/22)</td>
<td>15,952</td>
<td>44,321</td>
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<td>Week 10 (6/23-6/29)</td>
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<td>68,094</td>
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<td>Week 11 6/30</td>
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<td>7/1</td>
<td>6,043</td>
<td>13,554</td>
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<td>Week 11 Subtotal</td>
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<td>53,276</td>
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<td>Total</td>
<td>378,866</td>
<td>866,248</td>
<td>2,462,276</td>
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</table>

- **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.
“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

- 159 unique partners
- 53 executed cCRADAs
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”


Keynote Speakers

Dr. Keith Yamamoto
Executive Vice Chancellor for Research, UCSF

Dr. Maurizio Vecchione
Executive Vice President, Global Good Research

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)

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.
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.
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.

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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