Session 1: Keynote Speaker and Scientific Background to Meeting

Rapid (and Precise) COVID-19 Vaccine Development: Proof-of-Principle for Prototype Pathogen Preparedness and Response

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Deputy Director, Vaccine Research Center
National Institute of Allergy and Infectious Diseases (NIAID)
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While the frequency of pandemic threats seems to be increasing, we fortunately have new tools and technologies to make vaccines with more precision and speed. These advances make possible a more proactive approach to pandemic preparedness and response. There are ~26 virus families associated with human infection from which the next pandemic threat will likely arise. Within each relevant virus family, a database of information with accompanying reagents, assays, and animal models could be developed for prototypic viruses based on properties of tropism, transmission routes, and other distinguishing features of pathogenesis. Candidate vaccine approaches could be designed based on virus structure, transmission dynamics, entry requirements, and replication strategy. The rapid development of vaccines for COVID-19 were a direct consequence of the prototype pathogen approach for pandemic preparedness. Work on the Middle East Respiratory Syndrome (MERS)-CoV over the last 7 years was informed by structure-based immunogen-design concepts established for respiratory syncytial virus (RSV) Fusion protein (F) subunit vaccines, and focused on solving coronavirus spike structures, defining mechanisms of CoV neutralization, and evaluating MERS CoV vaccine candidates in collaboration with a commercial mRNA manufacturer. Prior spike protein engineering experience resulted in rapid sequence selection and using the mRNA manufacturing platform provided rapid GMP production a COVID-19 mRNA vaccine in record time. This candidate was tested in mice in ~25 days and humans in ~65 days from the time sequence was released. The product was tested in a 30,000 person phase 3 trial and shown to be 95% effective 10 months after sequence release and was granted Emergency Use Authorization by the FDA a month later. The proactive preparation not only facilitated rapid vaccine development and evaluation but provided stabilized spike protein reagents that were the basis for developing serological assays and isolating potent human neutralizing mAbs that have also been approved for prevention and therapy.

Rapid Retuning of the Pittsburgh Regional Biocontainment BSL-3 Laboratory to Support Pre-Clinical COVID-19 Studies

Paul Duprex, Ph.D.
Director, Center for Vaccine Research
University of Pittsburgh

When a novel coronavirus emerged late 2019 neither it, nor the disease it caused, had a name. Now severe acute respiratory syndrome (SARS) coronavirus (CoV)-2 and coronavirus disease (COVID)-19 are terms used daily across the world. Since pathogens continue to emerge from animal reservoirs readiness is vital to allow work on new viruses like SARS-CoV-2 to begin immediately. National Biocontainment Laboratories (NBLs) and Regional Biocontainment Laboratories (RBLs) provide Biosafety Level (BSL)-4/-3/-2 and BSL-3/-2 biocontainment facilities, respectively, for research on biodefense and emerging infectious disease agents. Their mandated role is twofold, first to conduct research on biodefense and emerging infectious disease agents and second, to be available and prepared to assist national, state, and local public health efforts in the event of a bioterrorism or infectious disease emergency. The COVID-19 pandemic is such a crisis.

The Center for Vaccine Research (CVR) at the University of Pittsburgh has an integral RBL as part of the institute. Capabilities include state-of-the-art cell, tissue and animal multimodal imaging, aerobiology and expertize working with a wide range of bacterial and viral pathogens. As SARS-CoV-2 emerged and the global COVID-19 pandemic ensued in 2020 the focus of CVR switched. Virologists, immunologists, bacteriologists, aerobiologists, cell biologists, biomedical engineers and clinicians pivoted to focus on COVID-19 science. This was underpinned by colleagues in Environmental Health and Safety (EH&S), the Division of Laboratory Animal Research (DLAR) and RBL Facilities who rapidly responded to the needs to the infection biologists to undertake *in vitro* and *in* vivo studies with this new BSL-3 agent. Collectively this resulted in the rapid establishment of four animal models of COVID-19 disease and supported pre-clinical studies for antibodies, nanobodies and vaccine-candidates. Ultimately, the pandemic starts as a virological problem. Therefore, significant effort is being expended on the identification and functional characterization of variants, variants of interest and variants of concern. Underpinning all of these efforts is an extensive and established laboratory animal research program. Lessons learned during the COVID-19 pandemic will be discussed.

Session 2: Ramping Up: Animals and Other Resources for Infectious Disease Research – Part 1

The COVID-19 Pandemic: The Triumphs and Challenges of Vaccine Development and Use of Animal Models in the Midst of a Pandemic

Ian N. Moore, D.V.M., Ph.D., DACVP
Investigative Veterinary Pathologist and Section Chief, Infectious Disease Pathogenesis Section (IDPS)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)

In 2020, the rise of a global SARS-CoV-2 (COVID) pandemic reshaped, and forever altered, the state of the world, the associated daily activities, and general human interactions. In early 2020, the National Institutes of Health's (NIH) Infectious Disease Pathogenesis Section (IDPS) accepted a role on the team of NIH researchers (in collaboration with the pharmaceutical company Moderna) to help in the development of an mRNA vaccine that would be used to combat the ongoing global COVID pandemic. In an already challenging and limited environment, Dr. Ian Moore, an investigative veterinary pathologist and head of the IDPS, began the process of evaluating the pre-clinical tissue samples to determine safety, efficacy and for the presence of adverse pathology. These pre-clinical assessments laid the path for the start of large-scale, in-human, clinical trials, and

submission of data to the FDA in search of Emergency Use Approval (EUA). During this 10-month process, the IDPS evaluated samples that encompassed multiple species including NHPs, mice and hamsters. While the resulting assessment and evaluation were positive and protective, there were some inherent challenges related to carrying out these processes in the middle of a pandemic. This presentation will briefly discuss the pathologic outcomes between these animal models and some of the pathology tools and tips used to assess outcomes. These challenges were also compounded by the need to process high numbers of research samples along with the need to still consider the social-distancing needs of laboratory staff and collaborators. Ultimately, generating accurate data on a tight timeline, during a pandemic, in response to that very pandemic, was a unique and challenging experience in addition to an extremely gratifying process that conveyed many valuable lessons.

Bringing together stakeholders: users and resources

Franziska B. Grieder, D.V.M., Ph.D.
Director, Office of Research Infrastructure Programs (ORIP)
Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)
National Institutes of Health (NIH)

In any emergency, such as a pandemic or a natural disaster, a rapid response is highly desirable, but in certain settings a rapid response is challenging, if not impossible. Concerted efforts in early 2020 in response to the SARS-CoV-2/COVID-19 health crisis (COVID pandemic) led the research community to recognize the urgent need to secure and organize animal models for studies aimed at understanding the pathogenesis, therapeutic identification and refinement, and vaccine development against SARS-CoV-2. Among the different animal models available, for many research projects, non-human primates (NHP) are recognized as a critical resource. Rhesus monkeys are the most used NHP species for COVID studies. Their limited availability presented a significant challenge to research institutions, investigators, and policy makers alike. Addressing this situation, it became critically important to identify available NHP resources and strategically plan for future supplies. This approach required an open dialogue between those groups producing and holding the research NHPs, the NHP resources and breeders, and the research investigators planning the strategic studies that utilize the limited supply of NHPs to address and respond to the pandemic. Coordinated exchange of information and priority setting is critical for an effective response addressing a crisis such as the COVID pandemic.

Lessons Learned: NHP Supply

Kurt Derfler, M.B.A.
Executive Director of Operations, Charles River Labs

As research to combat COVID-19 accelerated, the demand for non-human primates to complete critical studies also increased. US commercial suppliers of this important resource faced unprecedented challenges to meet this demand. This presentation reviews some of the challenges that were faced as well as some lessons learned to get in front of the next pandemic.

COVID-19 Rodent Model Development in CRISPR Age: Challenges

Stephen Festin, Ph.D.
Director, Scientific and Commercial Development
Corporate Research Models and Services
Charles River Laboratories

Nonhuman Primate Importation During the SARS-CoV-2 Pandemic

Gale Galland, D.V.M., M.S., DACVPM
Veterinary Medical Officer, Zoonoses Team
Quarantine Border Health Services Branch
Division of Global Migration and Quarantine
U.S. Center for Disease Control (CDC)

CDC regulates the importation of nonhuman primates (NHPs). The regulations are in Title 42 of the Code of Federal Regulations §71.53 (42CFR71.53). NHPs can only be imported by facilities that are registered and approved by CDC and only for science, education, or exhibition. CDC keeps a database of information about NHP shipments including numbers of animals, country of origin, species, etc. Comparison of data collected in fiscal year (FY) 2019 and FY 2020 shows a greater than 21% decrease in the total number of NHPs imported and a shift in the main country of origin from China to Cambodia. Cynomolgus macaques are still the primary species imported. The total number of African green monkeys imported, although still relatively low, has increased by over 155% between FY 2019 and FY2020.

Session 3: Ramping Up Animal Based Infectious Disease Research – Part 2

Occupational Health in a Pandemic:

Maureen Thompson, BSN, RN, COHN, RBP(ABSA)
Safety Officer, Yerkes National Primate Research Center
Associate Director, Environmental Health and Safety Office
Emory University

The presentation will discuss the importance of a comprehensive Occupational Health Program in animal research. The role of the Occupational Health Program in the rapid expansion of A/BSL-3 SARS-CoV-2 research as well as the management of potential personnel outbreaks will be reviewed. We will also look at the pandemic's impact on resources and demands on the work force. We will review the tools and processes developed for contact tracing, employee testing and new ways to deliver services and provide support during this unprecedented time. We will also share lessons learned that may enhance preparedness for future pandemics.

Risk Assessment and Biosafety Support for SARS-CoV-2 and COVID-19 Research: Challenges in established ABSL-2 and ABSL-3 research programs

Molly S. Stitt-Fischer, Ph.D., CPH, CBSP, SM(NRCM) and Rebecca Lingenfelter, MSPH
University Biosafety Officer/Associate Biosafety Officer and Alternate Responsible Official for Select Agents
Department of Environmental Health and Safety (EHS)
University of Pittsburgh

The University of Pittsburgh has had a pandemic preparedness plan as part of the larger University-wide emergency response and continuity of operations plans since 2007. This plan has been reviewed, revised, and used to inform other entity response plans, including animal care and use disaster response plans for our large, well-established animal research program. The University also has a substantial BSL-3/ABSL-3 research program including the NIAID-funded Regional Biocontainment Laboratory (RBL). In February 2020, the University's pandemic preparedness plan and Emergency Operations Center were activated SARS-CoV-2 research began in the RBL in response to the rapidly progressing COVID-19 pandemic. While established research and preparedness programs allowed the University to support critical COVID-19 studies, even during state-wide stay-at-home orders, unexpected challenges required rapid risk assessments and implementation of mitigation measures. This presentation will share lessons learned during work with an emerging pathogen in our RBL, as well as risk assessments used to support redistribution/rationing of scarce PPE, cleaning and disinfection procedures for laboratory and animal facilities, and strategies to provide training and safety information for researchers beginning COVID-19-associated work, including those without extensive experience in virology, and animal models. Through sharing the University's experiences during these unprecedented circumstances we hope to provide examples of emergent issues for other entities to consider in future pandemic planning efforts, as well as identify areas where additional local, state, and national support could strengthen our preparedness for response to emerging pathogens.

Session 4: Animal Research During COVID-19: Challenges and Opportunities to Address Future Pandemics

Public Messaging and Communications About Animal-Based Research During the COVID-19 Pandemic

James O'Reilly, B.A.
President, Massachusetts Society for Medical Research (MSMR)

The COVID-19 pandemic has illustrated how critical the role of animal research is to developing treatments and vaccines in the face of this global public health crisis. But the pandemic has also been exploited by animal activist groups who are using the circumstances to ramp up their calls for an end to animal-based medical research. This session will examine some of the tactics that have been used by activist groups to attack medical research institutions, and how to develop messaging and response strategies to better educate the public about the vital role of animals in medical research.

Virus Sequence Data During an Outbreak

Eneida Hatcher, Ph.D.
Contractor, National Center for Biotechnology Information
National Library of Medicine (NLM)
National Institutes of Health (NIH)

As a viral disease outbreak progresses, genomic sequence data can support different types of experiments and public health responses. A newly emerging virus may benefit from the context provided by related viruses. As an outbreak develops and sequencing efforts ramp up, an abundance of data creates challenges in submission processing, identifying patterns in the data and selecting datasets appropriate for experiments, and for surveillance efforts. I will be presenting some of the lessons the we have learned over the course of several outbreaks, and what we have done in response to those challenges.

The nonhuman primate model of SARS-CoV-2 to test therapeutic strategies: overcoming challenges and obstacles towards proof of concept

Koen Van Rompay, D.V.M., Ph.D.
Full Research Virologist, California National Primate Research Center (CNPRC)
UC Davis

Nonhuman primates are an important animal model for SARS-CoV-2 vaccine and therapeutic research. This presentation will cover the challenges of developing a nonhuman primate model of COVID-19 as well as give an overview of the current SARS-CoV-2 therapeutic research being done in nonhuman primates, include the latest findings from therapy studies for antiviral drugs, antibodies and anti-inflammatories. Results from these nonhuman primate studies provide proof-of-concept and guidance for ongoing and future clinical trials.

Fast tracking animal model development, collaborations, and research to deliver preclinical data for vaccine antigen selection

Isis Kanevsky, Ph.D.
Director, Vaccine Research Unit
Pfizer

An overview of the pre-clinical journey during Pfizer's project light speed, which focused on the rapid delivery of a COVID-19 mRNA vaccine. From review of relevant animal models, securing resources, and designing studies, to the final selection of antigens for pivotal clinical trials. Unprecedented speed, agility and collaborations were required to design, formulate, and evaluate antigens and bring us to Emergency Use Approval in December of 2020.

Management of a Nonhuman Primate Colony during SARS-CoV-2

Joyce Cohen, V.M.D., DACLAM
Associate Director, Division of Animal Resources
Yerkes National Primate Research Center
Emory University

In this session, Dr. Cohen will provide an overview of managing a large nonhuman primate colony during the COVID-19 pandemic. She will focus on the National Primate Research Centers' (NPRCs) responses to the situation and highlight how the different centers navigated the pandemic to manage their nonhuman primate

colonies in order to both protect the animals from natural transmission of SARS-CoV-2 as well as employees while on site. Dr. Cohen will also give an overview of the methods rapidly developed at the NPRCs to screen nonhuman primate colonies for SARS-CoV-2 as well as how the NPRCs pivoted to quickly support COVID-19 research.

Session 5: Resiliency in Animal Research Operations – COVID-19 Lessons Learned

Maintaining animal research continuity in the time of COVID-19

Michael J. Huerkamp, D.V.M., DACLAM
Executive Director, Division of Animal Resources (DAR)
Emory University

The speaker will discuss emergency preparedness and planning, the activation and use of the pandemic component of a plan, experiences with animal research ramp-down and restoration, managing communications, and accounts of success and otherwise. The presentation will then set the stage for ensuing speakers to cover select topics in more detail and elicit the participation of attendees to contribute their experiences and perspectives via the concluding panel discussion.

Resiliency in Animal Research Operations – COVID19 Lessons Learned: Direct Staffing Impacts

CDR Temeri Wilder-Kofie, D.V.M., MPH, DACLAM
Facility Veterinarian, Comparative Medicine Branch (CMB)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)

This session will discuss the fear and morale of animal care staff during the coronavirus pandemic and mitigation of these responses by leadership. Various incentive strategies implemented by government and academic entities will be shared with the audience, as well as training challenges faced during this time.

Resiliency in Animal Research Operations: Laboratory Animal Program Operations and Management Impacts

Jill Ascher, M.A., D.V.M., MPH, DACLAM
Director, Division of Veterinary Resources (DVR)
Office of Research Services (ORS)
National Institutes of Health (NIH)

The COVID-19 Pandemic has presented many challenges for continued smooth operation of Laboratory Animal Programs. There were many immediate concerns requiring quick thinking and planning. Maintaining an adequate workforce, and carefully maneuvering animal care staff through animal facilities, ensuring their safety and minimizing spread of the virus among the work force, while keeping workload manageable for staff has been particularly difficult. Preserving adequate supplies of everything needed to run the animal program from hand sanitizer, PPE, animal feed and bedding, disinfectants and many other supplies has proven to be problematic, too. Keeping staff informed and constant communication with stakeholders in general has been very important. Once the possibility of COVID-19 vaccination became a reality, supporting staff by informing them about websites where they might go to try to register for vaccination, and holding information sessions regarding what to expect when being vaccinated, has been helpful. My brief talk will touch on the aspects above

and other aspects required for continued and uninterrupted operation of a large, centrally-managed animal program during the COVID-19 Pandemic.

Impact of the COVID-19 Pandemic on Animal Research

Lori Palley, D.V.M., DACLAM
Assistant Director of Veterinary Services, Center for Comparative Medicine (CCM)
Massachusetts General Hospital (MGH)

In pandemic planning, ensuring the safety and well-being of personnel and research animals is paramount. With rapid evolving information on the SARS-CoV-2 virus, continuity planning to minimize disruptions in animal research was and continues to be an unprecedented challenge for the laboratory animal research community. The goal of this presentation is to share with you a firsthand approach as well as approaches from other academic laboratory animal research institutional responses to the COVID-19 pandemic, with a focus on the impact on animal research operations. Strategies for addressing continuity planning for researcher and animal care staffing along with daily activities, safety of personnel working in the animal facility, and research support services will be shared. A robust communication plan and an agile workforce are key to implementing effective continuity plans.

Financial Impact of the COVID-19 Pandemic on Academic Animal Care Programs

Lucy Kennedy, D.V.M., DACLAM
Assistant Director for Clinical Services and Assistant Attending Veterinarian,
Unit for Laboratory Animal Medicine (ULAM)
University of Michigan

The COVID-19 pandemic impacted animal care departments significantly in several ways, not the least of which was financially. In the initial months, universities and hospital systems balanced the need to incentivize a stressed staff while making changes to faculty and staff salaries and benefits to minimize the economic loss that was projected. For many animal facilities, drops in rodent cage census and increases in cost of PPE and other supplies contributed to the economic stress of the year. Here, we discuss the financial impacts of the COVID-19 pandemic on academic animal care departments, considerations for what we learned through the year, and thoughts on how to prepare for future similar events.

Evolving Prioritizations of *In Vivo* Research in Pharma During the COVID-19 Pandemic

Sean Maguire, V.M.D., M.S., MRCVS, DACLAM
Comparative & Translational Sciences Director & Associate Fellow
GlaxoSmithKline (GSK)

While there are many similarities in the response of in vivo research facilities during the pandemic I will discuss prioritizations and considerations from the Pharma perspective focusing on aspects that are particular to in vivo research in the context of drug discovery and development. Wide engagement of diverse stakeholders drove continue/stop/ start decisions and related due diligence efforts. Our responses and related decision-making processes evolved from the initial response to current day while meeting both the commitments and participation in the larger societal response to the pandemic as well as patient and program needs.

Integrating the Institution's COVID-19 Response Plan into the Research Animal Program

Stephen Denny, D.V.M., M.S., DACLAM, DACVPM
Director, Office of Animal Care and Use (OACU)
Office of Intramural Research (OIR)
National Institutes of Health (NIH)

As the COVID-19 pandemic progressed through 2020, research animal programs were faced with the additional operational challenge of integrating the institution's COVID-19 prevention and safety measures into their operating plans and procedures. In many cases, as more COVID-19 response measures were released, the research animal program's operations instituted new communications strategies and procedural changes to accommodate the integration of these COVID-19 safety measures while they continued to meet their institute's research goals. This presentation describes some of the research animal program communication strategies and changes implemented during the past year and is intended to provide a starting point for future discussions aimed at identifying additional examples of effective communication strategies animal programs may consider applying in future pandemic situations.