Ad Hoc Group Weekly COVID-19 Follow Up

August 6, 2020

In this time of the COVID-19 pandemic, we will be publishing an additional weekly update focused on COVID-19 to highlight related NIH actions and guidance as well as activities from the Ad Hoc Group community. As always, please forward any relevant items to Christa Wagner (chwagner@aamc.org) for inclusion in the publication!

Congressional and NIH News

Ad Hoc Letter Urges Funds for NIH in Next COVID-19 Relief Package

The Ad Hoc Group for Medical Research sent an August 6 letter urging Congressional and White House leadership to include emergency supplemental funds for NIH in the next COVID-19 emergency supplemental spending package. The letter urges negotiators to work quickly to "finalize a bipartisan agreement and to support emergency funding of at least $15.5 billion for the National Institutes of Health (NIH), as proposed in the Senate Health Education and Liability Protection and Schools (HEALS) Act." The letter also emphasizes the importance of NIH funding in supporting the economy, noting, "Emergency funding to support the federal biomedical research enterprise will help efforts to sustain and restore the nation's economic health broadly, while also aiding early career investigators who are particularly susceptible to career disruptions as a result of the pandemic."

NIH Utilizing AI For COVID-19 Diagnosis, Treatment, and Monitoring

The National Institute of Biomedical Imaging and Bioengineering (NIBIB) has launched the Medical Imaging and Data Resource Center (MIDRC), "an ambitious effort that will harness the power of artificial intelligence (AI) and medical imaging to fight COVID-19," according to an August 5 NIH news release. MIDRC will facilitate efficient and flexible collection, analysis, and dissemination of clinical imaging and associated data, "allowing researchers to evaluate both lung and cardiac tissue data, ask critical research questions, and develop predictive COVID-19 imaging signatures that can be delivered to healthcare providers," added NIBIB Scientific Program Lead Guoying Liu, PhD.

NIH Launches Two Antibody Treatment Trials

NIH announced on August 4 the launch of two clinical trials receiving support through the ACTIV and Operation Warp Speed partnerships to test antibody treatments for COVID-19, one Phase 2 trial for mild and moderate disease, and a Phase 3 trial for hospitalized COVID-19 patients . The Phase 2 Trial, ACTIV-2, will study the safety and efficacy of new COVID-19 therapeutics, including a synthetic monoclonal antibody, on COVID-19 patients who do not require hospitalization. "Using an antibody generated by the immune system of a recovered COVID-19 patient gives us a jump start on finding a safe and effective

therapeutic," said National Institute of Allergy and Infectious Diseases Director Anthony S. Fauci, M.D. "Investigating a variety of different therapeutics, including monoclonal antibodies, will help ensure that we advance towards an effective treatment for people suffering from COVID-19 disease as quickly as possible."

The Phase 3 trail, or ACTIV-3, aims to study an investigational monoclonal antibody in approximately 300 hospitalized volunteers. "Studying the impact of this investigational therapeutic on multiple patient populations at the same time is critical to determining whether it can help COVID-19 patients with differing levels of disease severity," said National Institute of Allergy and Infectious Diseases Director Anthony S. Fauci, M.D. "These concurrent trials have the potential to yield significant and comprehensive clinical data," he concluded.

COVID-19 Vaccine Shows Promise in Mouse Study

Research published on August 5 shows that a vaccine developed by NIAID and Moderna Inc. protects mice from SARS-CoV-2 infection, according to an NIH news release . The results show that several different doses of vaccine followed by exposure to virus at different times after vaccination provided protection from SARS-CoV-2 infection. These results build upon prior results from studies in nonhuman primates and Phase 1 clinical trials. The authors also describe how their prior research on a candidate MERS-CoV vaccine paved the way for a rapid response to the COVID-19 outbreak. "This is a demonstration of how the power of new technology-driven concepts like synthetic vaccinology facilitates a vaccine development program that can be initiated with pathogen sequences alone," the authors write.

COVID-19 and Child and Maternal Health

A July 30 blog post from NIH Director Francis Collins, MD, PhD, summarizes a recent interview with National Institute of Child Health and Human Development (NICHD) Director Diana Bianchi, MD, where the NIH leaders discussed the different impacts of SARS-CoV-2 on children compared to adults. Dr. Bianchi discussed what is currently known about infection rates and types of symptoms experienced by children, as well as suggestions for schools grappling with reopening this fall. The NIH leaders also discussed the impacts on vulnerable populations including minorities and children with disabilities as well as pregnant women.

Updates to NIH Applicant and Grantee COVID-19 Resources

NIH Office of Extramural Research staff on July 30 summarized recent updates to the COVID-19: Information for NIH Applicants and Recipients of NIH Funding webpage. Recent updates include an infographic describing the peer review process, guidance for applicants preparing for the fall 2020 due dates, an updated list of COVID-19 funding opportunities, and updated animal welfare FAQs.

Ad Hoc Member Resources

COVID-19 - Back to Campus: A Course on COVID-19 Safety

The Association of American Medical Colleges (AAMC) has collaborated with member institutions and CITI Program to launch a complimentary course to train research faculty and team members, research staff, students, and other staff at medical schools and research organizations on COVID-19 safety as they return to campus this fall. The

highlights of the course include a discussion of recommendations from NIH, CDC, and the Occupational Safety and Health Administration, as well as optional modules on specific research areas. Organizations may subscribe to this free course by October 1, and learners will receive a CITI Program completion report as evidence of successful training. Download a demo and learn more about the course here.

Upcoming Events

Inclusion Across the Lifespan Workshop – September 2

NIH is hosting the second in a series of Inclusion Across the Lifespan workshops to provide lessons learned regarding the inclusion of pediatric and older populations in clinical studies, with evidence-based practical advice to the scientific community. The workshop will bring together individuals with a variety of backgrounds in clinical study development and execution, with focus on pediatric and geriatric populations, and consideration of special populations across the life course. The workshop will take place on Wednesday, September 2, from 10:30am – 5:30pm EST. Please register in advance.

Virtual Rally for Medical Research – Sept. 16-17

The Rally for Medical Research is held every September and includes more than 300 national organizations coming together in support of to call on our nation's policymakers to make funding for National Institutes of Health (NIH) a national priority and raise awareness about the importance of continued investment in medical research that leads to more progress, more hope, and more lives saved. This year's event will be held virtually on September 16-17. For more information and to register, please visit https://rallyformedicalresearch.org.

Virtual NIH Regional Seminar – October 27-30

NIH is making plans for a virtual regional seminar on program funding and grants administration this fall. The event will take place from October 27-30. The agenda is currently under development, but a sample of potential sessions can be found here. Registration details will be on the Regional Seminars website when available.

NIH COVID-19 Resources

NIH COVID-19 resource for applicants and grantees including guidance for various aspects of research and grant application processes, as well as FAQs and COVID-19 funding opportunities.

COVID-19 "Updates History" webpage that details relevant updates for applicants and grantees by date.

FAQ document on COVID-19 flexibilities related to policies and programs affecting the grants process.

Funding opportunities specific to COVID-19 lists active and expired funding opportunities across NIH related to SARS-CoV-2/COVID-19 research.

HHS COVID-19 awards tracking website including data on awards made by all HHS awarding agencies with supplemental appropriations.

Job Postings

ASM Seeks a Regulatory Affairs Specialist

The American Society for Microbiology (ASM)'s Policy and Advocacy Department seeks an experienced Regulatory Affairs Specialist to strengthen its presence with federal agencies, specifically CMS and FDA, and proactively identify opportunities for ASM federal policy engagement on clinical and regulatory matters. This person will monitor, analyze, and report on regulatory activity that has the potential to affect the microbial sciences and clinical microbiology community in assigned policy areas, and work with ASM members and staff to develop position statements, testimony, and regulatory comments. View the full job description and apply here. For more information about ASM, go to: www.asm.org

Please Note: *If you have information of interest to the NIH advocacy community that you would like to share with the Ad Hoc Group, please forward it to Christa Wagner at chwagner@aamc.org or Tannaz Rasouli at trasouli@aamc.org.*