Influenza scientists at five sites in the United States are to receive funding from the National Institute of Allergy and Infectious Diseases (NIAID) to collaborate with investigators around the globe in a network designed to advance understanding of influenza viruses and how they cause disease.

In addition to basic research, investigators in the Centers of Excellence for Influenza Research and Surveillance (CEIRS) network also conduct domestic and international influenza surveillance studies with an emphasis on rapid characterization of viruses that have the potential to cause pandemics. The first CEIRS network was launched in 2007 by NIAID, part of the NIH. NIAID announced awards of the new contracts to continue the program for seven years.

The geographic range of sample collection sites will be more tightly focused than previously on those regions where new influenza viruses are likely to emerge and the network will further integrate basic research with surveillance data gathering, said CEIRS project officer Diane Post, Ph.D., of NIAID’s Division of Microbiology and Infectious Diseases.

“The CEIRS network exemplifies NIAID’s dual mission of conducting basic and applied influenza research, while maintaining the ability to respond rapidly in the event of an emerging public health threat,” said NIAID Director Anthony S. Fauci, M.D. “CEIRS investigators have contributed greatly to our understanding of how influenza viruses emerge from wild and domestic animals, their adaptation to and global circulation throughout the human population and the interplay between the viruses and human immune responses.” Dr. Fauci added that the CEIRS network also played a critical role in the nation’s response to the 2009 H1N1 influenza pandemic by, for example, quickly characterizing the virus and performing pre-clinical testing of candidate vaccines.

Four of the new CEIRS contracts are to institutions that had received a 2007 award. One institution, Johns Hopkins University, will establish a new center. All will conduct surveillance and basic research projects. The network has a global reach, with collaborations established or planned at more than two dozen sites in Asia, Southeast Asia, the Middle East, South America, Europe and Australia. Funding for the first year of the contracts will total approximately $23 million.

"Proposed work from all five centers involves new and exciting research programs that hold the promise to answer fundamental questions pertaining to influenza in animals and people," said Dr. Post.

For more information on this study, click here.
UPDATES FROM NCATS

On May 16, 2014, the National Institutes of Health (NIH) will hold a joint meeting of the national Center for Advancing Translational Sciences (NCATS) Advisory Council and Cures Acceleration Network (CAN) Review Board. This joint meeting will feature presentations by NCATS leadership, the CAN Review Board, and invited guests. Presentations will include a Director’s Report, a presentation by the NCATS Advisory Council Working Group on the IOM CTSA Program Report, and proposed CAN initiatives for Fiscal Year 2015. Council subcommittees also will report on 1) patient engagement; 2) partnerships with pharmaceutical and biotechnology companies, and venture capital firms; and 3) medical technologies. In addition, NCATS staff will present a Concept Clearance of proposed initiatives for consideration and approval by Council. For more information or a complete videocast of the meeting, please click here.

On March 6, 2014, the NIH hosted a webinar for small businesses in the life science sector. The NIH SBIR/STTR Pre-Submission Update Webinar provided participants with information on how the recent Reauthorization changes to NIH’s SBIR and STTR programs can affect a small business’ application in advance of the next receipt date. NIH’s SBIR/STTR Program Coordinator Dr. Matthew Portnoy discussed the registration and submission process for the SBIR and STTR programs, common submission errors, eligibility requirements for small businesses including new changes, SBIR Direct Phase II, switching between SBIR and STTR, and other relevant updates. For more information on the webinar including a complete videocast, transcript, and additional SBIR/STTR resources, please click here.

PULMONARY ALLERGY DRUGS ADVISORY COMMITTEE

On February 25, 2014, the Pulmonary Allergy Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee held a joint meeting to discuss data submitted by Armstrong Pharmaceuticals, Inc., to support a new drug application (NDA) 205920, for over-the-counter (OTC) marketing of epinephrine inhalation aerosol 125 microgram (mcg)/actuation (proposed trade name Primatene HFA), for temporary relief of mild symptoms of intermittent asthma for consumers 12 years of age and older. The committee was asked to consider whether the data support an acceptable risk/benefit profile of the epinephrine inhaler for use by OTC consumers. For more information on this meeting, please click here.

VACCINES AND RELATED BIOLOGICAL PRODUCTS ADVISORY COMMITTEE

On March 20, the Vaccines and Related Biological Products Advisory Committee held an open meeting to hear updates of the research programs in the Laboratory of Respiratory and Special Pathogens, Division of Bacterial, Parasitic and Allergenic Products, and in the Laboratory of Hepatitis Viruses, Division of Viral Products, Center for Biologics Evaluation and Research, FDA. For more information on the meeting, including briefing materials and a transcript, please click here.

NONPRESCRIPTION DRUGS ADVISORY COMMITTEE

On May 2, the Nonprescription Drugs Advisory Committee will meet to discuss data submitted by MSD Consumer Care, Inc., to support a new drug application (NDA) 204804 for over-the-counter (OTC) marketing of montelukast 10 milligram (mg) tablets (proposed trade name SINGULAIR Allergy). The proposed OTC use is "temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: Nasal congestion, runny nose, itchy, watery eyes, sneezing, itching of the nose." The applicant proposes to label the product for OTC use in adults 18 years and older. Efficacy and safety data, as well as results of consumer studies, will be discussed. The committee will be asked to consider whether the data support an acceptable risk/benefit profile for the nonprescription use by OTC consumers. For more information on the meeting, including briefing materials and webcast information, please click here.
**NIAID FUNDING ANNOUNCEMENTS**

PA-14-102 *Innovative Technologies and Assays in Support of HIV Cure Research (R41/R42)* — January 8, 2017

PA-14-041 *Clinical Trial Planning Grant for Interventions and Services to Improve Treatment and Prevention of HIV/AIDS (R34)* — January 8, 2017

PAR-14-122 *Integrated Preclinical/ Clinical AIDS Vaccine Development Program (U19)* — March 14, 2015

RFA-AI-14-028 *Modeling Immunity for Biodefense (U19)* — July 19, 2014

RFA-AI-14-021 *Targeting Latently Infected Cells Without Reactivation (R01)* — July 16, 2014

RFA-AI-14-003 *Consortium for Food Allergy Research (U19)* — June 20, 2014

For more information or to find more funding opportunities, please click [here](#).

**NEW TECHNOLOGIES AVAILABLE FOR LICENSING FROM THE NIH OFFICE OF TECHNOLOGY TRANSFER**

**Human Influenza Virus Real-time RT-PCR: Detection and Discrimination of Influenza A (H3N2) Variant from Seasonal Influenza A (H3N2) Viruses, Including H3y and Seasonal H3 Assays**

This invention relates to methods of rapidly detecting influenza, including differentiating between type and subtype. CDC researchers have developed a rapid, accurate, real-time RT-PCR assay that has several advantages over culture and serological tests, which require 5 to 14 days for completion; this assay can also be easily implemented in kit form. The increased numbers of human infection of H3N2 variant virus has led to a need for a highly sensitive and specific assay for the diagnosis and confirmation of the H3N2 variant virus.

**The Use of alpha-4 beta-7 integrin Inhibitors to Inhibit HIV Transmission and Infection**

This invention involves the use of inhibitors of alpha-4 beta-7 (a4b7) integrin to inhibit HIV transmission/infection, as a prophylactic to inhibit onset of the acute stage of HIV infection or to treat HIV infection. a4b7 integrin is a multifaceted target for HIV infection and recent studies indicate that it is important for establishing HIV infection through multiple paths. Studies indicate that: 1) CD4 T-cells present in vaginal and anal mucosa have high levels of a4b7 integrin, making CD4 T-cells permissive to HIV infection; 2) a4b7 integrin is important for cell to cell transmission of HIV; 3) a4b7 integrin is used to dysregulate the host humoral response to HIV; and 4) HIV acts on a4b7 integrin through an epitope in V2 loop of GP120, identified as important for HIV vaccine protection. Additionally, primate studies indicate that a4b7 integrin inhibition of HIV infection preserves gut-associated lymphoid tissue (GALT) generally destroyed during the acute phase of HIV infection.

**Treating or Inhibiting JC Polyomavirus Infections and JC Polyomavirus-Associated Progressive Multifocal Leukoencephalopathy**

Available for licensing are novel findings to generate immune response to JC polyomavirus (JCV). An immunogenic composition with a single JCV subtype VP1 polypeptide generates neutralizing antibodies to all JCV subtypes, including JCV with variant VP1 polypeptides. The invention is useful for the prevention, treatment, or inhibition of JCV infection and JCV-associated pathologies, such as progressive multifocal leukoencephalopathy.

To learn more about these technologies and find others available for licensing, please click [here](#).

**PATIENT ORGANIZATION EVENTS**

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<tr>
<th>International AIDS Society</th>
<th>HIV Medicine Association</th>
<th>International Society for Antiviral Research</th>
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| HIV Drug Therapy in the Americas 2014  
May 7-10, 2014  
Rio de Janeiro, Brazil | 8th Annual ACTHIV Conference for the Treatment of HIV  
May 8-10, 2014  
Denver, CO | 27th International Conference on Antiviral Research  
May 15-16, 2014 — Raleigh, NC |

Click [here](#) for more details.  
Click [here](#) for more details.  
Click [here](#) for more details.
**UPDATE FROM NASDAQ**

**Bruce E. Aust** is Executive Vice President of the Corporate Client Group at NASDAQ OMX. In this role, he oversees NASDAQ’s new listings and capital market business as well as global business development and relationship management with its 3,200 listed companies. Below, Mr. Aust provides an update on the state of the market.

The 2014 U.S. IPO market is off to its strongest start in seven years, and despite a recent market sell-off, we expect to surpass the 100th IPO milestone by the end of April. A combined 40 companies from the healthcare and biotech sectors have come to the public markets in the U.S. so far this year, leading all industries in this current surge of new listings. Four of the top five best performing IPOs of 2014 so far come from the biotech industry and have returned a combined average increase of 64 percent from their offer price, well above the market average return for all U.S. IPOs to-date, according to data compiled by Renaissance Capital.

This momentum has come on the heels of the single strongest year for IPOs since before the financial crisis, with 244 IPOs on U.S. exchanges in 2013, raising $57 billion. This is a substantial increase from 2012, which saw 130 IPOs and $43 billion in total capital raised. According to an analysis from Thomson Reuters, investors attributed the recent outperformance of the biotech industry vs. the S&P 500 and NASDAQ Composite to an improved regulatory environment; successful drug launches; an accommodating financing environment and interest from generalists and index ETFs in the sector.

Although market volatility, interest rates and investors’ appetite for risk are typical bellwethers for an uptick in IPO activity, a new factor has been the JOBS Act, which NASDAQ OMX lobbied heavily for on behalf of the industry. Companies with less than $1 billion in annual revenue can now file confidentially with the SEC as “emerging growth companies” (EGCs) – a new issuer category – and JOBS Act provisions have reduced a number of the regulatory barriers and financial disclosure requirements that had previously prevented companies from tapping the public markets for new capital. Over 90 percent of NASDAQ’s 126 IPOs in 2013 and 94 percent of NASDAQ’s 62 IPOs in 2014 to-date filed as EGCs. It has been incredibly encouraging to see so many private growth companies – particularly from the biotech industry – using the “IPO on-ramp” that has resulted from the JOBS Act to transition to the public markets.

In addition to our support of the biotech and greater healthcare industry in the capital markets and inside the beltway, earlier this year saw the launch of the NASDAQ Private Market LLC. The platform will serve as a new marketplace for private growth companies, including those from the biotech sector, to have an efficient and secure portal to raise capital, control secondary transactions and manage their equity-related functions. Qualifying private companies, typically several years away from an IPO, will be able to connect to a global network of registered broker-dealers who represent qualified institutional buyers as well as family offices and other accredited investors. By providing growth companies with a stable platform for liquidity and control of the market for their private shares, management can keep their focus on developing their revolutionary drug therapy or innovative products instead of rushing into the IPO process before they are ready.

Given that we cannot easily forecast the IPO environment, we must continue to support emerging growth companies with stable ways to access liquidity to promote the innovation needed for the biotech industry to remain globally competitive. We are proud to be the exchange venue of choice for the industry and to support its companies at every stage of their growth with the solutions necessary to successfully navigate the capital markets.

**HOUSE PASSES TICK SIZE LEGISLATION**

On February 11, the House of Representatives passed the Small Cap Liquidity Reform Act (H.R. 3448) by a 412-4 margin. Under current U.S. Securities and Exchange Commission (SEC) rules, all securities on the public market are priced in $0.01 increments. This minimum trading increment is known as the “tick size.” This bill, sponsored by Reps. Duffy (R-WI) and Carney (D-DE) would institute a five-year pilot program to allow small issuers to choose a larger tick size (either $0.05 or $0.10) in order to spur trading activity in their stock. Companies with annual revenues of less than $750 million would be eligible for the pilot program.

BIO strongly supports a tick size pilot program that will grant flexibility to growing companies and increase the liquidity and capital availability necessary for emerging biotechs to be successful on the public market. To read BIO’s endorsement of the Small Cap Liquidity Reform Act, please click here.
XBRL BILL INTRODUCED AND APPROVED BY COMMITTEE

On March 6, Reps. Hurt (R-VA) and Sewell (D-AL) introduced H.R. 4164, the Small Company Disclosure Simplification Act. This bill would grant emerging growth companies an exemption from eXtensible Business Reporting Language (XBRL) reporting, an onerous burden that duplicates company filings in an electronic format and requires small businesses to pay for an outside contractor to complete their quarterly reports. It would also institute a temporary XBRL exemption for companies with annual revenues below $250 million to give the SEC time to study and potentially improve the compliance mechanism for smaller companies. The House Financial Services Committee approved H.R. 4164 on March 14 with a bipartisan 51-5 vote. To read BIO’s letter of support, please click here.

BIO RELEASES PRINCIPLES ON CLINICAL TRIAL DATA SHARING

On March 25, BIO reaffirmed and broadened its long-standing commitment to improving human health through the development of innovative therapies by releasing Principles on Clinical Trial Data Sharing, which were adopted by its Health Section Governing Board. BIO President and CEO Jim Greenwood stated, “BIO recognizes that responsible clinical trial data sharing advances public health and scientific discourse, honors research participants’ expectations of privacy through informed consent, and promotes biomedical innovation. These Principles reflect our support for these goals, while maintaining incentives to invest in biomedical research and recognizing the human and financial resource constraints of small, pre-revenue enterprises.”

BIO members currently share research data in a number of ways, routinely publishing their clinical trials in peer-reviewed scientific journals and presenting their results at scientific meetings and workshops. These Principles reaffirm BIO’s support for these efforts, and represent a commitment to make additional information available to the public, qualified researchers, and patients participating in clinical trials.

“We believe these Principles will enhance scientific knowledge to advance public health and patient care. We remain committed to working with the broader scientific community to develop knowledge that will improve drug development, enhance public health, and reinforce public confidence in the safety and efficacy of our medicines,” said Greenwood.

For more information or to read BIO’s Principles on Clinical Trial Data Sharing, please click here.

ALLERGY/INFECTIOUS DISEASE/ANTIVIRAL-FOCUSED LEGISLATION

H.R. 4260—Ryan White Patient Equity and Choice Act
This bill would ensure the Ryan White Comprehensive AIDS Resources Emergency Act program is as effective as possible in preventing the spread of the HIV epidemic by ensuring that funding allocations are evidenced-based.

Sponsor: Rep. Renee Ellmers (R-NC-2)
Status: Referred to the Subcommittee on Health

H.R. 3630—Cure for AIDS Act of 2013
This bill would direct the Secretary of Defense, through the Congressionally Directed Medical Research Program, to establish and support an accelerated research program dedicated to discovering a cure for HIV/AIDS.

Sponsor: Rep. James Himes (D-CT-4)
Status: Referred to the Subcommittee on Health
BIO TESTIFIES ON PCAOB AUDIT REPORT PROPOSAL

On April 2, BIO’s Executive Vice President for Emerging Companies, Cartier Esham, testified before the Public Company Accounting Oversight Board (PCAOB) about its proposed changes to the auditor’s reporting model. In December, BIO provided comment to the PCAOB urging it to reconsider its proposed audit rules that would substantially burden growing public biotech companies. BIO was invited to testify about the effect that the proposed critical audit matters standard would have on small companies. Cartier’s testimony opposed the PCAOB’s recommendations to institute an onerous critical audit matters standard in small company audit procedures. She also urged the PCAOB and the SEC not to apply the proposed rule to the audits of emerging growth companies as defined by the JOBS Act.

To read Cartier’s testimony to the PCAOB, please click here.

BIO 2014 PARTNERING UPDATE

BIO’s partnering system opened for the BIO 2014 International Convention on April 3. Since then, partnering activity has been high, exceeding the standard set last year. BIO is predicting that 2014 will see a record number of meetings, and partnering participants are encouraged to start early this year, as the competition for meetings will be heightened. To register for BIO 2014 and the BIO Business Forum, click here.

To help human health biopharma and biotech companies accelerate and improve their partnering strategy, BIO has teamed with Thomson Reuters, who will leverage their Recap and Cortellis databases and staffs to offer 60 minutes of complimentary consulting to Business Forum registrants. Interested parties can sign up here.