December 2013 ACTS Connection

ACTS Connection

The Affordable Care Act – A Translational Research Project?

The Affordable Care Act promises to bring the largest change to the American health care system that has been seen in several decades. Will the change be good or bad? While many choose to argue this point, Dr. Harry P Selker, ACTS Vice President for Healthcare Implementation, Delivery and Policy Research, and colleagues make a compelling argument that changes in health care delivery should be viewed as a translational research experiment that requires rigorous scientific evaluation. A link to their article in Science and Translational Medicine can be found here.

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Translational Science 2014, sponsored by the Association for Clinical and Translational Science (ACTS) and the American Federation for Medical

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Research (AFMR), will be held from April 9-11, 2014, at the Omni Shoreham Hotel in Washington D.C. Keynote Speakers are:

- Dr. Christopher Austin, Director of the National Center for Advancing Clinical and Translational Science (NCATS)
- Dr. Bruce Gellin of the National Vaccine Program Office, US Department of Health and Human Services
- Dr. John McKew of the National Center for Advancing Clinical and Translational Science (NCATS) and Dr. Barry Coller of Rockefeller University
- Dr. William Chin, Executive Vice President, Science and Regulatory Affairs, PhRMA

The program will include Mock Study Sections and Concurrent Sessions on "Scientific Misconduct: Pitfalls for the Junior Investigator," "How to Write a K Grant," "K to R - Mentoring to Success," "Pediatrics/Child Health," Academic Advancement for Translational Researchers," "Serendipity in Science". New this year, a limited number of abstracts will be selected for oral presentations, in addition to poster sessions.

Early registration will be available until February 28, 2014. Register now and save!

Submit your abstract by January 29, 2014. We look forward to seeing you at Translational Science 2014.

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Washington Update

When Congress acted to end the recent government shutdown and raise the country's debt-ceiling, the legislation that was passed called for a House and Senate Conference Committee on the federal budget. For months, the House and Senate have been moving down divergent paths with regards to funding for government programs. The House has advanced spending proposals that seek to cut federal funding below sequestration levels. Alternatively, the Senate is seeking the end to sequestration and provide a restoration of funding for many programs. The Conference Committee's only mandate is to try to reconcile the House and Senate budgets so that there is a consensus framework for federal spending moving forward.

While the deadline for the Committee to put forth a draft agreement is fast approaching, lawmakers remain optimistic that a deal can be reached. Although negotiations are taking place behind closed-doors, it is reported that in addition to agreeing on a top-line number for federal spending the Committee is trying to close some tax loop holes and advance certain entitlement reforms to programs like Social Security.

Most importantly, the House and Senate are presently holding fiscal year (FY) 2014 appropriations bills pending the outcome of the Conference Committee's effort. If the Committee puts forth a budget proposal that is supported by both chambers, appropriators will need to modify their bills to align with the new spending guidelines. Presently, all federal programs are operating under a stop-gap spending measure known as a Continuing Resolution (CR), which is set to expire in mid-January. Congress will need to take some action on FY 2014 appropriations before the CR expires.

The great hope of the current Conference Committee effort is that lawmakers will ultimately support a proposal that eliminates sequestration. Due to the tireless outreach of medical research advocates and other advocates, there is a growing consensus on Capitol Hill that sequestration needs to be fixed. The work of medical research advocates received some additional support recently when the defense industry called on Congress to end sequestration due to the devastating impact indiscriminate funding cuts are having on our ability to advance defense research. Hopefully, the expanding chorus of voices calling to end sequestration will be heard by a critical mass of Congress ahead of the completion of FY 2014 appropriations.

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Share Your Passion, Share Your Experience: Become Involved in ACTS!

Involvement in ACTS is an ideal way to advance your profession while continuing to expand the clinical and translational science field. ACTS volunteers are provided with the unique opportunity to influence the direction and future of our organization.

The ACTS Board of Directors is currently seeking qualified candidates to fill three Director-at-Large positions. All members in good standing are eligible to nominate themselves or others for this position. If you would like to serve as a Director-at-Large or recommend someone else for the position, please visit ACTS's Nomination webpage to fill out a nomination form by January 6, 2014.

ACTS is also seeking volunteers to serve on our many committees. Visit our volunteer webpage for more information on the committees and to indicate your interest in a committee position.

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The *ACTS Connection* Editors Want Your Feedback

ACTS Connection Editor, Dr. Satish R. Raj, MD, MSCI, and Associate Editor, Dr. Quinn Wells, MD, PharmD, MSCI, are interested in hearing about ways that *ACTS Connection* could provide even more value to our readers.

Please feel free to email Dr. Raj or Dr. Wells with your comments or suggestions

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Translational Science News

Pamela M. McInnes Named National Center for Advancing Translational Sciences Deputy Director

The National Center for Advancing Translational Sciences (NCATS) has named Pamela M. McInnes as its new deputy director. McInnes, who will join NCATS in January 2014, currently serves as director of the Division of Extramural Research at the National

Institute of Dental and Craniofacial Research (NIDCR). "Her recruitment is a key milestone in our building the NCATS organization into a catalyst for transformational change in translational science, getting new treatments to more patients more quickly," says NCATS Director Christopher P. Austin. McInnes' NIDCR responsibilities included extramural research that covered large and complex clinical and population-based trials.

From "Pamela M. McInnes Named National Center for Advancing Translational Sciences Deputy Director"
NIH News (12/03/13)

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Pfizer to Expand Clinical Data Access to Researchers, Patients

Pfizer has announced it will be easier for independent researchers and patients to access information from its clinical trials. Starting in 2014, the company will make available easy-to-comprehend abstracts of its trial results to study participants who want to receive them. Trial participants also will be able to download all of their personal data extracted during the study. For medical and scientific researchers, Pfizer says it will consider requests for access to its trial information, providing anonymous patient data available for high-quality scientific reviews, and it will ensure transparency by creating an independent review panel of academic scientists with the authority to supersede a Pfizer veto or partial approval of clinical data access to researchers.

From "Pfizer to Expand Clinical Data Access to Researchers, Patients"
Reuters (12/04/13) Berkrot, Bill

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Genetic Alliance & PhRMA Partner to Drive Patient-Focused Drug Development

The Genetic Alliance and the Pharmaceutical Research and Manufacturers of America have launched an initiative to examine the use of a technology-based, crowdsourcing strategy to facilitate patient-focused drug development. The Genetic Alliance issued a request for proposals, after which it selected advocacy organizations representing three disease areas for public meetings in 2014 and 2015. The three disease areas are sickle cell disease; idiopathic pulmonary fibrosis; and irritable bowel syndrome, gastroparesis, and gastroesophageal reflux. "Using the Platform for Engaging Everyone Responsibly (PEER), there is an opportunity to demonstrate the power of a secure, crowdsourced approach to provide additional insight into patients' experience with a disease or condition," says Sharon Terry, president and CEO of Genetic Alliance.

From "Genetic Alliance & PhRMA Partner to Drive Patient-Focused Drug Development"
Genetic Engineering & Biotechnology News (12/05/13)

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Singapore Joins Global Translational Medicine Network as Asia-Pacific Hub

The Eureka Institute for Translational Medicine has signed a memorandum of understanding with SingHealth and Duke-NUS Graduate Medical School, which form Singapore's largest academic healthcare cluster. Eureka is a new global research network designed to facilitate the discovery of treatments and cures, and it includes academic medical institutes from Europe and North America. Researchers from the two institutions will gain access to knowledge, resources, and technologies from across the network to strengthen their ability to conduct globally impactful research. Additionally, researchers from the network will be offered places on the Eureka Institute's translational medicine certification program. Serving as network members, SingHealth and Duke-NUS will be able to help develop the course to make sure it addresses skill gaps relevant to Asia. "Translational Medicine is like a bridge which joins patients to research. It is a two-way bridge, as unmet medical needs inspire research, and research provides new solutions to fight disease. ... Eureka aims to address these problems innovatively and comprehensively," says Salvatore Albani, president, Eureka Institute for Translational Medicine.

From "Singapore Joins Global Translational Medicine Network as Asia-Pacific Hub"
EurekAlert (12/05/13)

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Cleveland Organizations Launch Institution for Medical Data Analysis

Three organizations--Case Western Reserve University, Cleveland Clinic, and University Hospitals--have formed the Institute of Computational Biology to better analyze vast amounts of medical data. The new institute will deploy technological infrastructure to allow researchers from the three institutions to assess existing clinical data for ways to improve treatment of patients and communities, officials say. "We can collect myriad genetics/genomics data from every one of our patients, but if we don't have the capability to convert that data into actionable information, we have gained nothing," said Paul DiCorleto, chair of Cleveland Clinic's Lerner Research Institute. "The Institute of Computational Biology will provide this capability with cutting-edge bioinformatics approaches." Geneticist Jonathan Haines has been named director of the institute and also serves as chair of the Department of Epidemiology and Biostatistics at Case Western Reserve University School of Medicine.

From "Cleveland Organizations Launch Institution for Medical Data Analysis"
Healthcare Informatics (11/13) Leventhal, Rajiv

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PCORI Approves Over $1B for Comparative Effectiveness Research in 2014-15

During a recent meeting in Atlanta, the board of governors of the Patient-Centered Outcomes Research Institute (PCORI) approved a two-year commitment to provide more than $1 billion in funding for comparative effectiveness research. This marks a major jump in funding from PCORI, which was created by the Affordable Care Act to promote research aimed at bringing down the cost of healthcare. PCORI estimates it will provide $400 million in grant funding by the end of 2013, and the November vote approved a projected $528 million in awards for 2014 and an operating budget of $182 million. Funds will be directed toward research in several areas, including health disparities, shared decision-making, chronic disease management, and research methods. The board also approved a 139-page methodology report, which provides guidelines for effective research. "Departures from basic good research practices are partially responsible for mismatches between the quality and relevance of the information research provides and the information patients need to make informed

clinical decisions," PCORI said in the report.

From "PCORI Approves Over $1B for Comparative Effectiveness Research in 2014-15"
Modern Healthcare (11/18/13) McKinney, Maureen

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Do Drug Companies Suffer From Premature Translation--and Can Google's Calico Cure It?

Medical commentator David Shaywitz says that the announcement of Calico--a Google-backed company devoted to carrying out the basic research necessary to address the issue of aging--has thrown into sharp contrast the divergent attitudes toward basic biological research and translation efforts to develop medicines and treatments. Calico has been lauded by many for making a long-term financial commitment to researching basic biology without the guarantee of an equivalent payoff. David Botstein, Calico's soon-to-be chief scientific officer, says that we still understand very little about the finer points of genetics and microbiology, and that building a solid foundation of such knowledge will allow for the development of better and more effective cures and treatments. However, others point out the value of translational research, even in the absence of many pieces of fundamental knowledge. "The challenge, clearly, is how to combine these perspectives, and benefit from both the fundamental rigor of basic science as well as the urgency associated with attempts to apply it," says Shaywitz.

From "Do Drug Companies Suffer From Premature Translation--and Can Google's Calico Cure It?"
Forbes (11/22/13) Shaywitz, David

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Simulators Help Build a Better Drug Trial

To improve how drug trials are designed, researchers are turning to robust computer simulators. Pharmaceutical firms hope computer simulators help them make correct choices, such as the number of people to test, the appropriate drug dose, and suitable trial duration. Simulators show researchers whether a certain set of test parameters will lead to a statistically significant result for a particular treatment. The researchers can keep fine-tuning their decisions until they design a test that accurately measures the effects of a drug. "If we had this five years ago, many of the recent high-risk drug failures" might not have occurred, asserts Diane Stephenson, executive director of the Coalition Against Major Diseases at the nonprofit Critical Path Institute. In June, the U.S. Food and Drug Administration and the European Medicines Agency endorsed the first simulator, developed by Critical Path Institute, for use in the development of treatments for Alzheimer's disease. Simulators are now being made for tuberculosis, Huntington's disease, and Parkinson's disease, according to Stephenson.

From "Simulators Help Build a Better Drug Trial"
Wall Street Journal (11/17/13) Rockoff, Jonathan D.

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Pediatric Research Gets Boost From New Bills Passed This Week by U.S. Congress

In November, Congress passed a number of health-related bills, including two that provide increased support for pediatric research. The Kids First Research Act of 2013 redirects $126 million over a 10-year period from the Presidential Election Campaign Fund to the the National Institutes of Health's Common Fund. The aim is to support multi-center pediatric research beginning in 2014. Another bill that was passed by Congress is the National Pediatric Research Network Act of 2013, which does not boost federal spending but enables the National Institutes of Health to support the creation of as many as 20 multi-center partnerships focusing on pediatric research, in particular rare pediatric disorders like cystic fibrosis and muscular dystrophy. "This is a way to support pediatric research in a more thoughtful and cost-effective manner," says Michael Konstan at University Hospitals Case Medical Center and UH Rainbow, referring to the National Pediatric Research Network Act. "By forming networks, we can focus on the most important areas." Akron Children's Hospital, Cincinnati Children's Hospital Medical Center, and Nationwide Children's Hospital in Columbus are part of a coalition that has been promoting the passage of the bills. By leveraging the centers' individual strengths, the networks will "markedly enhance the speed at which diagnostic and therapeutic studies are [created], while at the same time maintain the scientific rigor and focus on safety," says Michael Reed at Akron Children's Rebecca D. Considine Research Institute.

From "Pediatric Research Gets Boost From New Bills Passed This Week by U.S. Congress"
Cleveland Plain Dealer (OH) (11/15/13) Townsend, Angela

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Wall Street Journal's 'Trials' Project

For six years *The Wall Street Journal* has followed the struggle of parents and scientists to find a cure for Nieman-Pick Type C, a rare genetic disease that often takes the lives of its young patients. Chris Hempel, whose daughters Cassidy and Addison were diagnosed with NPC when they were three years old, and other parents have been fighting for years to get the Food and Drug Administration to recognize the potential of cyclodextrin--a sugar-based molecule used in air fresheners and as a food additive--to combat the disease. At the same time, a coalition of doctors was also pushing to find a cure for NPC, the sort of disease that is rarely pursued by pharmaceutical companies. The scientists included Christopher P. Austin, the first permanent director of the National Center for Advancing Translational Sciences (NCATS) at the National Institute of Health. Austin met Hempel at a 2007 meeting of scientists, researchers, and parents of kids with NPC. At the time Austin headed NIH's Chemical Genomics Center, a state-of-the-art lab that uses robotic systems to test thousands of compounds against rare diseases, and after the meeting he successfully pushed to have NPC tested at his lab. In the years since, Hempel has advocated for cyclodextrin, going so far as to independently test it on her children, and the restarted trials of the drug has become one of NCATS' first major projects.

From "Wall Street Journal's 'Trials' Project"
Wall Street Journal (11/14/13) Marcus, Amy Dockser

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Grant Opportunities

Ruth L. Kirschstein National Research Service Award (NRSA) Institutional

Research Training Grant (Parent T32)

The National Institutes of Health has announced the Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grants (T32), which are intended to boost predoctoral and postdoctoral research training and help ensure that a diverse and highly trained workforce is available to meet the nation's biomedical, behavioral, and clinical research agenda. The research training programs will include didactic, research, and career development components to help prepare recipients for careers that will have a significant impact on the health-related research needs of the country. Applications are due by Jan. 25, 2014.

From "Ruth L. Kirschstein National Research Service Award (NRSA) Institutional Research Training Grant (Parent T32)"
Grants.gov (12/09/13)

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Ruth L. Kirschstein National Research Service Award Short-Term Institutional Research Training Grant (Parent T35)

The National Institutes of Health (NIH) is accepting applications for the Ruth L. Kirschstein National Research Service Award Short-Term Institutional Research Training Grants (T35) to eligible, domestic institutions to develop and/or enhance research training opportunities for predoctoral students who are interested in careers in biomedical, behavioral or clinical research. A number of NIH Institutes and Centers use this program to support intensive, short-term research training experiences for health professional students during the summer. This program also aims to encourage training of graduate students in the physical or quantitative sciences to pursue research careers by short-term exposure to, and involvement in, the health-related sciences. Applications are due by Jan. 25, 2014.

From "Ruth L. Kirschstein National Research Service Award Short-Term Institutional Research Training Grant (Parent T35)"
Grants.gov (12/09/13)

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Indo-US Collaborative Program on Affordable Medical Devices (R03)

The National Institutes of Health has issued a funding opportunity announcement for an Indo-U.S. collaborative program on affordable medical devices. The program aims to encourage joint activities between U.S. and Indian scientists on affordable diagnostic and therapeutic technologies and address medical needs in low-resource settings, taking advantage of opportunities and technological advances, to aid the development of appropriate affordable medical devices. The coordinated program will involve collaborative, peer-reviewed research and technology development projects. Grants provided under this program will cover direct costs of up to $75,000 per year for two years. Applications are due by Jan. 23, 2014.

From "Indo-US Collaborative Program on Affordable Medical Devices (R03)"
NIH Grants (11/21/13)

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Macy Faculty Scholars

The Josiah Macy Jr. Foundation has issued a call for applications for the 2014 Macy Faculty Scholars Program. The program seeks to identify and nurture the careers of promising educational innovators in medicine and nursing. Scholars chosen for the program will receive salary support of $100,000 per year for two years, at least 50 percent protected time for two years to pursue educational projects, active mentorship by a senior faculty member at their institution, access to the program's national advisory committee, and opportunities to participate in Macy conferences and other national meetings. Applications are due by Feb. 26, 2014.

From "Macy Faculty Scholars"
Macy Foundation (11/14/13)

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Exceptional Unconventional Research Enabling Knowledge Acceleration (EUREKA) for Neuroscience and Disorders of the Nervous System (R01)

The National Institutes of Health (NIH) has issued a funding opportunity announcement (FOA) for innovative Research Project Grant (R01) applications addressing exceptionally novel hypotheses and/or remarkably difficult problems in neuroscience and disorders of the nervous system. The FOA--from the National Institute of Mental Health, National Institute on Aging, National Institute on Drug Abuse, and National Institute of Neurological Disorders and Stroke--notes that the "proposed research may have a high risk of failure, but it must promise results with especially high impact should it be successful." The EUREKA (Exceptional Unconventional Research Enabling Knowledge Acceleration) program seeks to promote innovative research that, if successful, will have an unusually high impact on the areas of science that are germane to the mission of one or more of the participating NIH Institutes. A letter of intent is due by Jan. 3, 2014.

From "Exceptional Unconventional Research Enabling Knowledge Acceleration (EUREKA) for Neuroscience and Disorders of the Nervous System (R01)"
NIH Grants (11/14/13)

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BRF: Fay/Frank Seed Grant Program

The Brain Research Foundation's Fay/Frank Seed Grant Program is offering funding for new research projects in the field of neuroscience that will likely lead to extramural funding from the National Institutes of Health or other outside funding sources. The foundation, which launched the program in 1981, has invited 29 U.S. institutions to nominate faculty to submit letters of intent for 2014 program funding. The program aims to support new and innovative projects, particularly those of junior faculty, who are working in new research directions. Letters of intent are due by Jan. 8, 2014.

From "BRF: Fay/Frank Seed Grant Program"
Brain Research Foundation (11/14/13)

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American Diabetes Association Mentor-Based Postdoctoral Minority Fellowship

Award

The American Diabetes Association's Training Award program supports postdoctoral fellows and students working toward doctoral degrees. The program aims to support the training of minority scientists who are underrepresented in the field of diabetes research. Applicants must identify as an eligible minority defined under the terms of this award, including African American; Hispanic or Latino; American Indian or Alaskan Native; and Native Hawaiian or Pacific Islander. Awards are $45,000 per year for two to three years. Applications are due by Jan. 15, 2014.

From "American Diabetes Association Mentor-Based Postdoctoral Minority Fellowship Award"
American Diabetes Association (11/07/13)

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