August 2014 Connection

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ACTS Seeks a New Executive Director

The Association for Clinical and Translational Science (ACTS), the leading professional and scientific organization in clinical and translational science seeks an accomplished **Executive Director** to lead and advance the organization's mission and achievements. Information about ACTS may be found at www.actscience.org.

ACTS seeks an **Executive Director** with knowledge of and experience with the complexities of clinical and translational research support and the interactions among academic health centers, industry, and state and federal funding agencies. In addition to submitting your resume online, please submit a cover letter that includes an executive summary explaining how you are positioned to effectively lead ACTS.
The ideal candidate will:

- have a passion for furthering clinical and translational science
- have management experience (ideally with translational science organizations)
- be a strategic thinker in terms of clinical research and the ACTS mission
- be an excellent communicator
- have experience in fiscal management
- supervise and lead management teams
- plan and lead the organization of the annual Translational Science meeting

Interested candidates should send their resume and a cover letter explaining how they are uniquely positioned to lead ACTS. Please send these to Mr. James Zaniello by August 31, 2014.

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The ACTS mission is to advance research and education in clinical and translational science to improve human health. For more information, visit actscience.org

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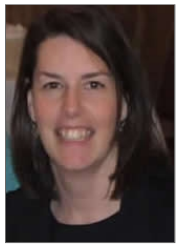
News from ACTS

Join the Education Administrators and Coordinators SIG

The ACTS recently approved a new Special Interest Group (SIG), the Education Administrators and Coordinators Group. The mission of this SIG will be to provide a forum for administrators, instructional designers, and coordinators of clinical and translational research education and career development programs to network and share best practices. Since 2003 this group has met annually at the Translational Science meeting in DC. Group leaders know from attendee feedback that networking among administrators and coordinators from institutions across the nation is invaluable. The hope is that this SIG will provide an extension of that networking as well as an opportunity to plan and provide more venues at the national meeting for administrator and coordinator training and collaboration. This new group will be co-chaired by Jennifer McKanry (jmckanry@dom.wustl.edu), Washington University, and Jeanne Dzekov McKean (dzekov@med.usc.edu), University of Southern California. They look forward to hearing suggestions from staff who develop and manage translational research training programs about how the business of this group could best fit their needs. The group hopes to hold regular conference calls and provide web forums as well as build upon its existing listserv. If you are interested in participating in the SIG or have ideas to share about how the SIG is formed, please reach out to the co-chairs.

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Washington Update

As Congress adjourns for the August summer recess, much work remains to finalize the twelve annual appropriations bills that fund federal programs. Lawmakers will return after Labor Day with limited time in session to make progress before recessing again for the November elections.

Fiscal Year (FY) 2015 begins on October 1st and legislators are likely to produce a stop-gap funding measure known as a continuing resolution or CR, which will maintain FY 2014 funding levels until after the elections. The outcome of these contests will play a significant role as legislators decide whether to finalize spending legislation during the lame-duck session at the end of the year, or leave it for the incoming 114th Congress to contend with in January.

The Labor-Health and Human Services-Education (L-HHS) Appropriations bill, which funds clinical and translational research and training and career development programs, is traditionally the most controversial and progress on the FY 2015 measure has been slow. The House Appropriations Committee has not produced a draft bill and there has been no committee action to this point. The Senate Appropriations Committee marked up its version of the bill in subcommittee, but the threat of politically-sensitive amendments abruptly halted plans for full committee consideration.

Chairwoman Barbara Mikulski (D-MD) took the unusual step of releasing a few of the draft appropriations bills, including the L-HHS bill and accompanying report, although the measures have not been officially approved by the full committee. Chairwoman Mikulski and retiring Senate L-HHS Subcommittee Chairman Tom Harkin (D-IA) hope that absent input from the House, the Senate L-HHS Subcommittee mark will provide key guidance on funding for health and education programs once a plan for finalizing the appropriations bills emerges. Most notably, the Senate measure calls for a meaningful funding increase for the National Institutes of Health and voices crucial support for the Agency for Healthcare Research and Quality, the Clinical and Translational Science Awards Program, the Institutional Development Awards Program, and other key federal programs.

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Opportunities for Collaborative Research at the NIH Clinical Center (U01)

The National Institutes of Health is accepting pre-applications for its Opportunities for Collaborative Research at the Clinical Center (U01) awards. The program seeks to strengthen translational research collaborations between extramural and intramural basic and clinical researchers. To be eligible for this program, the application must include at least one intramural scientist and some of the research must be conducted at the NIH Clinical Center. Projects are for three years and are renewable. Budgets are limited to $500,000 a year in direct costs, and funds should be designated to support project-related costs of the extramural PI, the intramural Co-PI, and the NIH Clinical Center. **Pre-applications for the next cycle are due December 10, 2014, and full applications are due March 20, 2015.**

Pre-Application FOA: http://grants.nih.gov/grants/guide/pa-files/PAR-13-357.html
Application FOA: http://grants.nih.gov/grants/guide/pa-files/PAR-13-358.html
Clinical Center Collaborations: http://clinicalcenter.nih.gov/translational-research-resources/index.html

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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

FDA Issues Informed Consent Guidance

Additional guidance has been issued by the Food and Drug Administration (FDA) on

obtaining informed consent for clinical trials, such as furnishing patients with a description of the trial, its risks, benefits, alternative treatments, confidentiality, and compensation in the event of injury. It also offers guidance on how investigators and institutional review boards can help ensure that informed consent is adequate and meets the FDA's requirements. The guidance calls for researchers to explain alternative treatments that participants might be able to receive if they were not involved in the research. The guidance also allows the disclosure of off-label uses of the drug being tested. Rosamond Rhodes at the Mount Sinai School of Medicine notes that the revised guidance includes a section recommending that trial participants be told the outcome of the trial. However, she says the guidance does not fully resolve what should be done when participants lack the capacity to consent themselves, such as children or people who are unconscious. "This document is full of language about a 'legal representative' [for such people], but most states have no laws designating who the legal representative is," Rhodes notes. For instance, New York's Family Healthcare Decision Act lets a patient-appointed proxy or family member make decisions on behalf of patients regarding their treatment, but it does not apply to decisions related to research participation.

From "FDA Issues Informed Consent Guidance"
MedPage Today (07/23/14) Frieden, Joyce

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Big Pharma Opens Up Big Data for Clinical Trials, Analytics

Big pharmaceutical companies are taking unprecedented steps toward opening their labs to clinical researchers and data analysts, much like healthcare providers who have learned that for the industry to advance, data must be shared. Stepping away from their traditional secrecy surrounding expensive drug development, companies are sharing clinical trial data and patient information in order to advance research and improve clinical outcomes. GlaxoSmithKline, for example, is opening its data to researchers in the hopes it will speed the process of bringing drugs to market and flagging dead ends and patient safety risks. The company--along with Bayer, Sanofi, Roche, and Lilly--uploads patient-level data from clinical trials into a web portal for researchers to submit proposals and request anonymized data. There are also other data delivery services and collaborations between companies like Optum and the Mayo Clinic, which provides access to data on 149 million UnitedHealth Group patients and 5 million Mayo patients. Thomson Reuters also offers clinical trial data though its Cortellis Clinical Trials Intelligence program, which includes data on drugs, biologics, biomarkers, diagnostics, and medical devices.

From "Big Pharma Opens Up Big Data for Clinical Trials, Analytics"
Health IT Analytics (07/23/14) Bresnick, Jennifer

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NIH's Translational Center Scores First Drug Acquisition by Pharma

Baxter International has acquired AesRx, a biotech firm developing Aes-103, a small molecule for treating sickle cell disease. The acquisition marks a success for the National Institutes of Health's (NIH's) three-year-old National Center for Advancing Translational Sciences (NCATS). "This is the first drug to make it out of that process," says NCATS Director Christopher Austin. "So it's a really nice validation" of the center's model. Aes-103 binds to hemoglobin and prevents red blood cells from sickling, and it has achieved pain reduction in patients in clinical trials. AesRx collaborated with NCATS and NIH's National Heart, Lung, and Blood Institute to move the drug through phase II trials. NIH also provided more than $5 million for clinical trials, among other funding. Austin says the sickle cell initiative was especially attractive because Aes-103 has unusual chemistry and a novel mechanism that made it excessively risky for most commercial enterprises.

From "NIH's Translational Center Scores First Drug Acquisition by Pharma"
Science (07/09/14) Kaiser, Jocelyn

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Medical Sleuths Seek Patients With Mystery Diseases, Offer New Tools

The National Institutes of Health (NIH) has launched a $43 million campaign to fund research into medical mysteries, or undiagnosed and misunderstood diseases. The funds are an expansion of the NIH's Undiagnosed Disease Network, which is expected to enroll at least 300 new patients by the summer of 2017. Their conditions have stumped some of the best physicians in the world, and could be caused by rarely-seen conditions, rare forms of common diseases, or diseases that have never before been included in medical literature. There will be some caused by infection or environmental exposure, and a great number will be rooted in the patient's genes, making the program a good opportunity for scientists to discover more about the human genome's role in causing and possibly curing disease. In the program's first six years, it diagnosed about 100 out of 600 patients, including two previously unknown diseases and 15 genes not previously linked with disease. Researchers joining the new phase of the project include those from Baylor College of Medicine, Boston Children's Hospital, Brigham and Women's Hospital, Massachusetts General Hospital, Duke University, Stanford University, UCLA, and Vanderbilt University Medical Center. Harvard Medical School will be the coordinating center for the network, in which a set of common practices will be developed for member institutions to select, evaluate, and diagnose patients.

From "Medical Sleuths Seek Patients With Mystery Diseases, Offer New Tools"
Los Angeles Times (07/01/14) Healy, Melissa

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Michael J. Fox Foundation Funds Research Project That Leverages NCATS Chemical Screening Approach and Resources

Support from the Michael J. Fox Foundation for Parkinson's Research is helping James Inglese, director of the National Center for Advancing Translational Sciences' (NCATS) Assay Development and Screening Technology Laboratory, and Richard Youle of the National Institute of Neurological Disorders and Stroke, to lead a project that harnesses NCATS' chemical screening resources. Over the past several years, Youle and his colleagues discovered a molecular pathway that appears to be involved in Parkinson's disease, while Inglese's group designs and creates assays that can be used to screen chemical libraries for compounds that have therapeutic potential in a specific disease. Sam Hasson, one of Youle's investigators, teamed with Inglese to develop an assay using neuron-like cells grown in a lab. Thereafter, the project team integrated a new screening technology developed by Inglese and his team called coincidence reporting. This method enabled the team to conduct quantitative high-throughput screening, or qHTS, with NCATS' chemical libraries to identify compounds

that increase parkin activity. The Michael J. Fox Foundation is funding efforts to develop assays, complete the screening, analyze the results, and conduct follow-up studies with the most promising compounds to narrow down a list of a small number of potential therapeutics, eventually to be tested in flies and mice. The goal is to test the best candidates for their effectiveness in treating Parkinson's in humans.

From "Michael J. Fox Foundation Funds Research Project That Leverages NCATS Chemical Screening Approach and Resources"
National Center for Advancing Translational Sciences (07/01/2014)

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A Blueprint for Helping Children With Rare Diseases

The major goal of the Food and Drug Administration Safety and Innovation Act (FDASIA), enacted two years ago, is to encourage the development of new treatments for children with rare diseases. The law directed the FDA to hold a meeting with stakeholders and discuss ways to encourage therapeutic developments, and to issue a strategic plan for achieving this goal. This research presents unique challenges: children may respond differently to treatments than adults, and there are ethical concerns about studying treatments in pediatric populations. The FDA's Strategic Plan for Accelerating the Development of Therapies for Pediatric Rare Diseases includes four objectives. The first objective is to enhance foundational and translational science and fill information gaps by fostering natural history studies for pediatric rare diseases, identifying unmet pediatric needs in device development, and issuing guidance for sponsors on common issues in rare-disease drug development. The second objective is to strengthen communication, collaboration, and partnering among agencies, governments, and private entities. The third objective is to promote the use of regulatory science for clinical trial design and performance. The final objective is to enhance the FDA's review process and further develop a structured approach to benefit-risk assessment in the drug review process.

From "A Blueprint for Helping Children With Rare Diseases"
FDA Voice blog (07/08/14) Warner, Jill Hartzler

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Ireland's First Rare Disease Plan Published

Ireland's Department of Health has published the National Rare Disease Plan for Ireland 2014 to 2018, which notes a higher recorded prevalence of certain rare autosomal recessive disorders in the country. Additionally, data from national and international rare disease registries indicate a different prevalence in Ireland for such disorders as cystic fibrosis and congenital anomaly. The report makes a total of 48 recommendations in the areas of information and research, prevention diagnosis and care, empowering and protecting patients, and implementation and monitoring. For instance, the report calls for all existing databases to be mobilized. Another recommendation calls for appropriate support to be given for the ongoing involvement of Irish registries in relevant European collaborations, including RARECARE and EUROCAT. In addition, the Department of Health and the Health Service Executive should establish a coherent system over five years to conduct broad epidemiological surveillance of rare diseases.

From "Ireland's First Rare Disease Plan Published"
Irish Medical News (07/21/14) Mulholland, Paul

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What Clinical Trials? Many Study Results Remain Under Wraps

A new study in PLOS One indicates that many studies are not disclosed to the public despite rising demand for drug makers and researchers to publish clinical trial results. The study found that nearly 30 percent of 400 randomly selected trials that were completed in 2008 had not been published in a medical journal or posted on the ClinicalTrials.gov four years later. The smaller Phase II trials that occur at the earlier stages of development and are funded exclusively by the pharmaceutical industry were less likely to be published, the study shows. The study authors estimate that results for hundreds of trials each year, potentially as many as 500, are not publicly disclosed.

From "What Clinical Trials? Many Study Results Remain Under Wraps"
Wall Street Journal (07/22/14) Silverman, Ed

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$2.5 Million Grant Will Establish Patient-Centered Outcomes Research Training Program at Einstein and Montefiore

The Agency for Healthcare Research and Quality has allocated a $2.5 million grant for Yeshiva University's Albert Einstein College of Medicine and Montefiore Medical Center to set up a patient-centered outcomes research (PCOR) training program. There will be three elements of the Einstein-Montefiore PCOR training program, including an immersion PCOR fellowship in which researchers and doctors will spend three months at Montefiore's Care Management Organization (CMO). "Montefiore's CMO is at the forefront of innovation in healthcare delivery, and uses evidence-based approaches to improve the 'Triple Aim': improved health, enhanced patient satisfaction and reduced costs," notes Einstein professor Urvashi Patel. "The PCOR fellows will both learn from, and contribute to, these innovations and improvements of our healthcare system." The training program's remaining elements are a certificate in PCOR and an advanced learning collaborative. The former focuses on a classroom curriculum that complies with PCOR methodology standards, covering such areas as qualitative research, research informatics, participatory research, and PCOR implementation and dissemination. The latter will provide a forum for teaching, learning, information sharing, debate, and methodology development.

From "$2.5 Million Grant Will Establish Patient-Centered Outcomes Research Training Program at Einstein and Montefiore"
EurekAlert (07/17/14)

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Grant Opportunities

Pilot Centers for Precision Disease Modeling (U54)

The National Institutes of Health (NIH) has issued a funding opportunity announcement (FOA) for cooperative agreement applications for Pilot Centers for Precision Disease Modeling. The goal of the centers is to support collaborative research

projects that connect current personalized medicine efforts in humans with advances in animal genomics and technologies for genetic manipulation and creation of interspecies somatic hybrids. The FOA is from the Division of Program Coordination, Planning, and Strategic Initiatives within NIH's Office of the Director. Applications are due by Oct. 1, 2014.

From "Pilot Centers for Precision Disease Modeling (U54)"
NIH Grants (07/25/14)

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AGA: Caroline Craig Augustyn & Damian Augustyn Award in Digestive Cancer

The American Gastroenterological Association is offering funding for young investigators who are focusing on digestive cancer. The Caroline Craig Augustyn & Damian Augustyn Award in Digestive Cancer provides $40,000 for one year for a young investigator, instructor, or research associate who holds a federal or non-federal career development award devoted to conducting research related to digestive cancer. The funds are to be used to support direct research-related activities and may be used to support a new endeavor or an on-going basic or clinical project. In addition, the research must be a departure from or an extension of the objectives of the funded career development award, so applications proposing some or all of the aims of the funded career development award will not be considered for funding under this award mechanism. Applications are due by Jan. 16, 2015.

From "AGA: Caroline Craig Augustyn & Damian Augustyn Award in Digestive Cancer"
American Gastroenterological Association (07/25/14)

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Genentech Age-Related Macular Degeneration Research Fellowships

The ARVO Foundation for Eye Research is offering research fellowships in the field of age-related macular degeneration (AMD). The fellowships, established in 2011, will provide one $40,000 grant to a research working in basic research in the understanding of AMD and a second $40,000 grant to a researcher working in translational AMD research focusing on therapeutics. The grants are available to newly established investigators who are age 45 or younger at the application deadline and received their MD, PhD or equivalent degree after June 2004. Applications are due by Sept. 30, 2014.

From "Genentech Age-Related Macular Degeneration Research Fellowships"
ARVO Foundation for Eye Research (07/25/14)

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Saving Tiny Hearts: Research Grant Application

The Saving tiny Hearts Society, which is dedicated to furthering grass roots research of congenital heart defects (CHDs), is calling for proposals for its research grant. Grants will be made only in one-year commitments, with totals not exceeding $75,000 in direct costs. The society said that priority will be given to hypothesis-driven research that will impact the lives of children and adults with CHD. Applications are due by Sept. 26, 2014.

From "Saving Tiny Hearts: Research Grant Application"
Saving tiny Hearts Society (07/25/14)

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Interstitial Cystitis Association Pilot Research Program

The Interstitial Cystitis Association (ICA) is offering a one-year award of $25,000 for novel and useful basic, clinical, or translational research about interstitial cystitis. Areas of interest for the ICA Pilot Research Grant include epidemiology/burden of disease (particularly in children), etiology of IC, serum or urine markers, treatment modalities, neurophysiology, pain management, pregnancy and IC, and diet and nutrition. Applications are due by Feb. 27, 2015.

From "Interstitial Cystitis Association Pilot Research Program"
Interstitial Cystitis Association (07/25/14)

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