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August 2013 Connection

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ACTS Introduces New Leadership Profiles for ACTS Connection

In order to more efficiently support the joint missions of translational research and training, three organizations recently merged to form the Association for Clinical and Translational Science (ACTS). ACTS was formed by the merger of the Association for Patient Oriented Research (APOR), the Association for Clinical Research Training (ACRT), and the Society for Clinical and Translational Science (SCTS). As a part of this merger, new executive and committee structures have been developed. Specifically, standing committees led by a Vice-President were created for Patient-Oriented and Early Translational Research, Clinical Investigator Education and Training, and Healthcare Implementation, Delivery and Policy Research.

Beginning this month *ACTS Connection* will begin a series introducing the ACTS leadership. Each month an ACTS officer will be featured and given an opportunity to discuss their role in ACTS, vision for the organization as a whole, and specifically their committee (as appropriate). This month, we begin the series by highlighting ACTS President Anantha Shekhar, M.D., Ph.D. from Indiana University.

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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

The Association for Clinical and Translational Science
 2025 M Street NW
 Suite 800
 Washington, DC 20036
 (202) 367-1253
info@actscience.org

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Dr. Shekhar is the founding Director of the Indiana Clinical and Translational Sciences Institute (CTSI), a statewide institute within the Indiana University School of Medicine, supported by a CTSA grant from the US National Institutes of Health, and established in 2008 as a joint partnership of Indiana, Purdue and Notre Dame Universities. The Institute's mission is to assist in the rapid translation of new discoveries into novel treatments. Dr. Shekhar is the Assistant Vice President of Research at Indiana University, and Associate Dean for Translational Research and the Raymond E. Houk Professor of Psychiatry, and Professor of Neurobiology and Pharmacology & Toxicology at the Indiana University School of Medicine. Dr. Shekhar obtained his medical degree from St. John's Medical College in Bangalore, India. After completing a psychiatry residency, a PhD in Neurobiology, and an NIMH fellowship at Indiana University School of Medicine, he joined the faculty at Indiana University School of Medicine. He is certified by the American Board of Psychiatry and Neurology.



In addition to his role in leading the statewide translational research initiative, Dr. Shekhar leads a successful basic and clinical research programs in the areas of stress, anxiety and neuropsychiatric disorders, funded by the NIH since 1989. His laboratory has developed translational models for several neuropsychiatric disorders, including panic, phobias, anxiety disorders, and depression. His discovery work focuses on the role of brain circuit abnormalities that could lead to neuropsychiatric disorders and has more recently extended these studies to the developing new treatments. He also established and directed a Clinical Neuroscience Research Center (NCRC) at Indiana University Department of Psychiatry from 1997 to 2007 where he directed multiple phase I and II studies in healthy and disease populations, as well as biomarker studies utilizing physiology and brain imaging methods. He has tested a number of novel compounds for efficacy studies initiated through investigational new drug applications. He has conducted many pharmacokinetic, pharmacogenetic, and Phase III studies of novel compounds in the treatment of anxiety disorders, depression and schizophrenia, and bipolar disorders. He has published more than 160 original scientific papers in leading basic and clinical journals. A number of grants from the National Institutes of Health, private foundations, and commercial collaborations currently support his research. He was a member of the Board of Scientific Advisors for the National Institute of Mental Health in 2007-2008, and currently serves as a member of the Advisory Board for Clinical Research at NIH. He is the current president of the Association for Clinical and Translational Sciences.

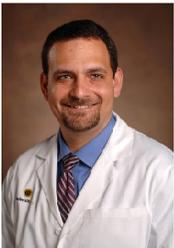
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ACTS Connection Has New Editors

The *ACTS Connection* team is happy to announce that Dr. Satish R. Raj, MD, MSCI, Associate Professor of Medicine and Pharmacology, Vanderbilt University, will serve as editor for *ACTS Connection*, and Dr. Quinn Wells, MD, PharmD, MSCI, Instructor of Medicine, Vanderbilt University, will serve as associate editor. Dr. Raj's research portfolio is focused on patient-oriented studies designed to understand pathophysiology and to find novel treatments for disorders of orthostatic intolerance. Dr. Raj currently serves on the Board of Directors for the ACTS. Dr. Wells' research interest focuses on the genomics and pharmacogenomics of cardiovascular disease and he sees patients in the Vanderbilt Center for Inherited Heart Disease. He is an early career investigator, and a recipient of an American Heart Association Fellow-to-Faculty Career Development Award.



Both Drs. Raj & Wells are interested in hearing about ways that *ACTS Connection* could provide even more value to our readers. Please feel free to email Dr. Raj (satish.raj@vanderbilt.edu) or Dr. Wells (Quinn.s.wells@vanderbilt.edu) with your comments or suggestions.



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Abstract Submission for Translational Science 2014 Opens in October

Translational Science 2014, to be held in Washington, DC, April 9-11, 2014, is excited to announce the opening of the abstract submission period beginning in October. Medical students, MD/PhD students, Residents, Fellows and Junior Faculty are invited to present their research and interact with many of the finest scientists in the world.

Outstanding submissions from all disciplines of medicine may have the opportunity to give an oral presentation or present their research in a poster session. Mentors are invited also to bring their students to present their abstract. Mark your calendars for April 9-11, 2014, for Translational Science 2014 at the Omni Shoreham Hotel in Washington, DC.

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Washington Update

Before adjourning for the August recess, Congress continued to work on several high-profile legislative topics. Most notably, the Senate Appropriations Committee marked up many of the annual spending bills, including the FY 2014 Labor-Health and Human Services-Education (LHHS) Appropriations bill. The Senate LHHS bill provides significant funding increases for federal medical research and healthcare programs. On the other side of the Capitol, the House has yet to put forward an FY 2014 LHHS measure. There have been numerous reports on infighting and disagreement among the chamber's Republicans on core spending and appropriations issues.

Along with uneven progress on FY 2014 appropriations, sequestration continues to be a key issue for the government's still-undefined fiscal policy. While a consensus seems to be building among legislators that some action needs to be taken, the two sides of the aisle do not appear close to an agreement. Several agencies such as the National Institutes of Health (NIH) and the Health Resources and Services Administration (HRSA) have issued FY 2013 operating plans that clearly demonstrate the negative impact of sequestration. Decreased funding is forcing key agencies to forgo opportunities to study diseases, improve public health, and address the nation's health

workforce challenges.

The White House and HHS are working feverishly to keep the implementation of the healthcare reform legislation on schedule. Several of the reform bill's key features—such as establishing state health insurance exchanges and requirements for individuals to purchase health insurance—are slated for January 1, 2014. As the Administration moves forward with its plans to overhaul healthcare delivery in this country, the House is leading efforts to reform how Medicare reimburses physicians for the services provided to program beneficiaries. The House Energy & Commerce Committee has put forward bipartisan legislation to replace the current sustainable growth rate system with a more consistent compensation scheme that incentivizes quality of care over quantity of services delivered.

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Translational Science News

Drug Companies Promise More Data Transparency

Major pharmaceutical companies have pledged to release detailed information about their drugs to external researchers. The decision was jointly announced by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations. The two groups developed the guidelines, which were unanimously approved by member companies, and are poised to take effect on January 1. The guidelines would apply to all new drugs and all new uses for existing drugs, whether approved in the United States or the European Union. In February, however, PhRMA issued a statement criticizing proponents of data sharing, in particular the sharing of "patient-level" clinical data. PhRMA said it would be irresponsible and spur second-guessing of regulatory agencies, "which would be disastrous for patients." Both the U.S. and EU industry groups have opposed a plan by the European Medicines Agency to make trial data public whenever a drug is approved; a similar effort to require such data disclosure is underway in the European Parliament. Drug manufacturers, meanwhile, have raised concerns that patient privacy could be undermined if the data were not properly redacted, and that competitors could mine the documents to gain an advantage. The industry plan calls for companies to be allowed to create external panels to consider requests from "qualified" researchers for a range of data and dossiers that drug companies keep on their drugs. They would also have to provide plans for how they seek to use the data.

From "Drug Companies Promise More Data Transparency"
New York Times (07/25/13) P. B6 Thomas, Katie

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Clinical Sequencing Studies Land Up to \$27M From NIH

The National Human Genome Research Institute (NHGRI) and the National Cancer Institute have awarded four new grants toward the study of genome sequencing in clinical care. Grants for projects total up to \$27 million and are being funded under the Clinical Sequencing Exploratory Research (CSER) program. The projects will investigate the use of genome sequencing to inform couples about reproductive risks, identify causes of development delays in childhood and share those findings with parents, and find genetic alterations that increase cancer risk. A fourth grant will support a coordinating center at the University of Washington that will assist the other projects based at the Kaiser Research Foundation and Seattle Children's Research Institute, Hudson-Alpha Institute for Biotechnology, and the University of Michigan. In their first year, these projects will receive approximately \$6.7 million; the eventual total funding will depend on the availability of funds, according to NHGRI. "Genome sequencing has vast potential to uncover new targets for therapy. We're continuing to learn how best to use genome sequence data to understand disease susceptibility and causation and to advance treatment," said Bradley Ozenberger, CSER program director and deputy director of NHGRI's Division of Genomic Medicine.

From "Clinical Sequencing Studies Land Up to \$27M From NIH"
GenomeWeb Daily News (07/23/13)

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NIH Gambles on Recycled Drugs

A total of nine teams won funding in June from the National Institutes of Health's National Center for Advancing Translational Sciences (NCATS) to see if abandoned drugs can be redirected toward new targets. The nine awards will share \$12.7 million this year. The projects will address conditions including alcoholism, schizophrenia, and calcified aortic valves in relation to eight drugs abandoned by pharmaceutical firms. The drug sracatinib, for instance, inhibits the Src family kinases, enzymes that are typically activated in cancer cells. The drug was first developed by AstraZeneca but was found to be marginally effective against cancer, prompting the company to abandon it after spending millions of dollars to develop it through early human trials that proved that it was safe. A team led by Stephen Strittmatter at Yale University will be able to move the drug quickly into testing in people with early-stage Alzheimer's disease and intends to launch a 24-person safety and dosing trial in August. If the results are good, NCATS will fund the effort for two more years to enable the scientists to conduct a double-blind, randomized, placebo-controlled trial with 159 participants. However, NCATS is prohibited by law from funding trials beyond early phase II, so additional money will have to come from another backer.

From "NIH Gambles on Recycled Drugs"
Nature (07/17/13) Wadman, Meredith

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The Price of Free Data

The Supreme Court's unanimous decision in June to back the Association for Molecular Pathology in its case against Myriad Genetics is expected to significantly impact the genetic testing industry and the open science movement. Biotech companies and academic labs will now be able to conduct their own experiments on BRCA1 and BRCA2 and develop cheaper tests for these genes. However, Myriad still retains control of its stockpile of patient data it has kept private since 2006. Multiple variants of BRCA1 and BRCA2 exist, and without details on the severity of those variants, health professionals cannot differentiate between a benign mutation and a problematic one. An initiative called Free the Data comprising several nonprofit and for-profit organizations hopes to make that data more accessible. Each Myriad client received a report with their genetic results that detailed the severity of their specific BRCA1 or BRCA2 variant, which Free the Data hopes to compile and make available online for doctors, patients, and genetic researchers. InVita, a genetic diagnostics firm and a founding partner of Free the

Data, hopes to leverage the valuable patient variant data that the group is collecting to create an all-in-one genetic test. The goal is to bring "comprehensive genetic testing to a billion people on the planet," according to InVita CEO Randy Scott. The company has already cataloged more than 32,000 genetic variants related to more than 500 genetic conditions in a database that is curated and updated regularly from scientific journals by staff scientists.

From "The Price of Free Data"
Bio-IT World (07/24/13) Luchette, Matt

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A Rare Disease Network Connecting Patients With Experts Highlights Hospitals' Knowledge Base

A new app that links patients with a global network of rare disease experts is also helping to highlight hospitals' knowledge base for rare diseases. DreamIt Health's SpeSo Health's network--which comprises physicians, clinicians, hospitals, and other institutions--references a data set of more than 6,000 rare diseases on its site. Users can search for a disease online, and the results include a list of hospitals with details such as the number of experts working on that disease at a hospital, how many clinical trials it is running for that disease, and the number of journal articles staff have authored. The site also gives scores for network influence, which is based on a combination of math and statistics related to publications, clinical trials, and other activities.

From "A Rare Disease Network Connecting Patients With Experts Highlights Hospitals' Knowledge Base"
MedCity News (07/24/13) Baum, Stephanie

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Why the Slow Take-Up of Comparative Effectiveness Research? It's Time and Money, Says a New PCORI Survey

The Patient Centered Outcomes Research Institute has unveiled a new survey indicating that both patients and clinicians want health research to focus on improving outcomes. A panel of healthcare providers discussed how findings could affect the structure and content of comparative effectiveness research (CER). They favor patient-centric dissemination strategies that position CER research within clinician workflows and include financial compensation for the time clinicians spend discussing compared treatments with their patients. The panel also cited the need to make systemic changes to workflow in electronic health records. Panel member Marc Boutin at the National Health Council said, "It comes down to the primary care physician and their receptivity to really understanding the patient in his or her own context, and to help apply the best evidence to that patient." Boutin added that patients need to be engaged early on in the process and that the research must be put in proper context.

From "Why the Slow Take-Up of Comparative Effectiveness Research? It's Time and Money, Says a New PCORI Survey"
PharmExec.com (07/16/13) Herman, Clark

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Mathematical Models Target Disease With Drugs Chosen by Your DNA

U.S. and Chinese scientists have developed statistical models to predict which drug is best for a particular person with a specific disease. Using a pharmacogenomic approach, researchers used a person's genes to explain the difference between how one person responds to a drug compared to another. A team led by Penn State College of Medicine's Rongling Wu concentrated on drug response and drug reaction, specifically pharmacokinetics, which influences the concentration of a drug reaching its target, and pharmacodynamics, which determines a drug's response. Metabolic, environmental, and developmental factors also impact medication response. The researchers formed a statistical analysis framework comprised of differential equations that simulate such variables as protein-protein and protein-DNA interactions a drug has in a patient. The framework characterizes a drug's absorption, distribution, and elimination properties to generate information on pharmacological targets, physiological pathways, and eventually, disease systems in patients. "The results from this framework will facilitate the quantitative prediction of the responses of individual subjects as well as the design of optimal drug treatments," the researchers noted in *Advanced Drug Delivery Reviews*. The research was supported by the National Center for Advancing Translational Sciences.

From "Mathematical Models Target Disease With Drugs Chosen by Your DNA"
Penn State News (07/16/13) Indivero, Victoria M.

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Improving Systematic Reviews of Animal Studies Will Help Translational Medicine

A recent study found that several new developments and initiatives have been unveiled that are designed to enhance the quality and translational value of animal research, which must continue with support from the wider scientific community. The researchers focused on the quality of study conduct, reporting, and replication; systematic reviews and meta-analyses; and study registration, publication bias, and data sharing. They said that systematic reviews of animal studies should be conducted routinely and that funding agencies should subsidize systematic reviews to ensure transparency as well as curb the waste of financial resources and unnecessary duplication of animal studies. They also called for the creation and funding of an international register for animal studies. "Improving the quality and translation of animal research requires cooperation from the wider scientific community, journals, researchers, regulators, funding bodies, peer reviewers, and patients," the authors wrote in *PLOS Medicine*.

From "Improving Systematic Reviews of Animal Studies Will Help Translational Medicine"
Science Codex (07/16/13)

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Assay Development Driving Personalized Medicine

On January 1, clinical laboratories began billing for more than 100 molecular pathology tests using new CPT codes in place of the earlier stacked-code system. The move triggered worries about the role of molecular testing in the clinical setting as R&D initiatives press on to achieve personalized medicine. "To make these tests available to

a wider audience they need to move from a Research Use Only (RUO) status to a clinical one," says Olive Joy Wolfe at Clinical Consultants. "This may require collaboration across laboratories, working with groups like the NCI (National Cancer Institute), and working closely with the FDA early on to facilitate the process." It is also necessary to identify the use of the test, such as diagnostics, therapy choices, or patient intervention, Wolfe says. Biomarker assays are often multistep, requiring a combination of instruments and techniques that the average laboratory technician might not be familiar with. Samir Hanash at MD Anderson Cancer Center says it is crucial to develop assays that are implementable while achieving the same level of sensitivity. As the number of biomarker assays available for the study and evaluation of human disease increases, so does the need to understand their clinical utility. For patient-selection biomarkers, the final assay platform should be compatible with FFPE-processed tumor tissue simply because that is what is most often available. Pharmacodynamics biomarkers, meanwhile, are used to establish that the compound is reaching its biological target. A key challenge is knowing which combination of tissue/readout/assay platform to use to ensure that the anticipated biological effect overcomes the expected intradonor variability emerging from both technical and biological sources.

From "Assay Development Driving Personalized Medicine"
Genetic Engineering & Biotechnology News (07/01/13) Vol. 33, No. 13 Labant, MaryAnn

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Grant Opportunities

Greenwall Foundation: Faculty Scholars Program in Bioethics

The Greenwall Foundation's Faculty Scholars Program in Bioethics aims to help junior faculty members carry out innovative bioethics research, supporting research that goes beyond current work in bioethics to help resolve pressing ethical issues in clinical care, biomedical research, and public policy. The award supports 50 percent of a scholar's salary plus benefits for three years, up to the National Institutes of Health cap, with 10 percent institutional costs for the salary and benefits. The foundation also provides \$5000 annually for limited project support and travel. A letter of intent for this program is due by Nov. 1, 2013.

From "Greenwall Foundation: Faculty Scholars Program in Bioethics"
Greenwall Foundation (07/25/13)

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NSF: Partnerships for Innovation: Accelerating Innovation Research-Technology Translation

The National Science Foundation's Partnerships for Innovation (PFI) program, part of the Division of Industrial Innovation and Partnerships, is an umbrella for two complementary subprograms: Accelerating Innovation Research (AIR) and Building Innovation Capacity. Both programs involve the movement of academic research discoveries into the marketplace, though each focuses on different stages along the innovation spectrum. PFI: AIR Technology Translation is the focus of this award, aimed at bridging the funding gap between existing research discoveries that validate relevant science and engineering fundamentals and their translation through proof-of-concept, prototype, or scale-up along a path toward commercialization and engage faculty and students in entrepreneurial/innovative thinking. A letter of intent for this award is due by Oct. 7, 2013, and the full proposal is due by Nov. 13, 2013.

From "NSF: Partnerships for Innovation: Accelerating Innovation Research- Technology Translation"
National Science Foundation (07/25/13)

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NIH Commits \$24 Million Annually for Big Data Centers of Excellence

The National Institutes of Health has announced that it will provide up to \$24 million per year for four years to fund the establishment of six to eight investigator-initiated Big Data to Knowledge Centers of Excellence, whose mission will be the development and distribution of new methods, software, and tools for sharing, integrating, analyzing, and managing data generated by biomedical research. Research in biomedical fields is increasingly generating massive data sets that can be difficult to manage and share, prompting NIH to launch the Big Data to Knowledge (BD2K) initiative in December 2012. The Centers of Excellence are the next step of that initiative. NIH Director Francis S. Collins says the goal of the centers will be "to help researchers translate data into knowledge that will advance discoveries and improve health, while reducing costs and redundancy." Applicants will need to identify a field of study and propose specific research in data science that aims to develop new methods, software, and tools for data integration and analysis, as well as database development and management, and data visualization and modeling. The centers will act as a consortium, building cooperatively on individual research efforts. Applications for the program are due by Nov. 20, 2013.

From "NIH Commits \$24 Million Annually for Big Data Centers of Excellence"
National Institutes of Health (07/22/13)

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Continuation of ChiLDReN, the Childhood Liver Disease Research Network (U01)

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has issued a funding opportunity announcement to continue the support of a Data Coordination Center and Clinical Centers of the Childhood Liver Disease Research and Education Network as the Childhood Liver Disease Research Network (ChiLDReN). ChiLDReN will continue clinical and translational research on rare pediatric liver diseases including Biliary Atresia; Alagille syndrome; alpha-1-antitrypsin deficiency; Progressive Familial Intrahepatic Cholestasis syndromes; Bile acid synthesis defects; Mitochondrial hepatopathies; Idiopathic Neonatal Hepatitis; and Cystic Fibrosis Liver Disease. NIDDK plans to commit \$6.5 million for up to 16 awards for fiscal year 2014. A letter of intent is due by Oct. 20, 2013, with the final application due on Nov. 20, 2013.

From "Continuation of ChiLDReN, the Childhood Liver Disease Research Network (U01)"
NIH Grants (07/18/13)

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Fondation Leducq: Transatlantic Networks of Excellence

The Fondation Leducq is awarding grants of up to \$6 million over five years for internationally collaborative research in cardiovascular and neurovascular disease as part of the Transatlantic Networks of Excellence in Cardiovascular Research Program. The program's goals include developing international cardiovascular and neurovascular research networks that benefit from a demonstrable collaborative advantage; advancing science in the areas of cardiovascular and neurovascular disease; applying the knowledge gained through research to promote the development of technology and therapeutics to improve human health; and supporting the career development of young investigators in cardiovascular and neurovascular disease. Participants should be affiliated with an academic research center in North America or Europe, and they must have expertise in cardiovascular or neurovascular disease or an appropriate related field. A letter of intent is due by Sept. 12, 2013.

From "Fondation Leducq: Transatlantic Networks of Excellence"
Fondation Leducq (07/18/13)

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American Diabetes Association and Lilly Clinical Research Award: Diabetes Care in Older Adults

The American Diabetes Association and Lilly Clinical Research Award: Diabetes Care in Older Adults will provide grant support for clinical and translation studies that aim to improve the evidence base and understanding of the goals, barriers, and effects of treatments and interventions the older adult population with diabetes. The program will provide funding for up to three awards, with each receiving a maximum of \$200,000 annually, for a total of \$550,000 over a three-year period. Applications are due by Sept. 16, 2013.

From "American Diabetes Association and Lilly Clinical Research Award: Diabetes Care in Older Adults"
American Diabetes Association (07/18/13)

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CDC: Mentored Research Scientist Development Award (K01)

The Centers for Disease Control and Prevention is seeking applications for a Mentored Research Scientist Development Award. The award provides support and 75 percent "protected time" for an intensive, supervised (mentored) career development experience in occupational health and safety research leading to research independence. The National Institute for Occupational Safety and Health Mentored Research Scientist Development Award (K01) aims to help ensure the availability of an adequate numbers of highly trained scientists and educators to address occupational safety and health critical issues. An applicant may request a budget for direct costs of up to \$100,000 per year. The closing date for applications is Sept. 2, 2015.

From "CDC: Mentored Research Scientist Development Award (K01)"
NIH Grants (07/03/13)

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Association for Clinical and Translational Science | 2025 M Street, NW, Suite 800 | Washington, DC 20036
Phone: (202) 367-1119 | Fax: (202) 367-2119 | email:info@actscience.org

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