ACTS Leadership Profile: Harry Shamoon, MD - Co-chair of the Program Committee for Translational Science 2014

Dr. Shamoon is Professor of Medicine (Endocrinology, Diabetes and Metabolism) and Associate Dean for Clinical & Translational Research at the Albert Einstein College of Medicine, and director of the Harold and Muriel Block Institute for Clinical & Translational Research at Einstein and Montefiore. Translational research has been at the core of Dr. Shamoon’s research and academic career. His long-standing focus was diabetes and metabolism, with a translational research component in type 1 diabetes and hypoglycemia counterregulation. In addition to his NIH-funded human metabolic research, he served as the Einstein PI for landmark diabetes clinical trials. Finally, as a member of Einstein Diabetes Research Center, he worked with investigators engaged in behavior, prevention, outcomes and effectiveness research. These diverse research perspectives have informed his academic leadership position and his role as PI of the Einstein-Montefiore CTSA. His personal touchstone is that “translation” takes place at multiple points in the processes of converting biomedical discovery to health outcomes, and that teams build the most innovative research programs.

Dr. Shamoon’s research team has studied the mechanisms and treatment for defective counterregulation of hypoglycemia. His team established the fundamental link between reduced epinephrine and glucagon secretion and impaired hepatic glucose production in response to hypoglycemia. Further studies elucidated the stimulus-specificity of the responses to hypoglycemia and the resultant defects in glucocorticoid counterregulation, as well as the contributions of hepatic glycogen metabolism and gluconeogenesis. In addition, he was a member of the national research teams that conducted the Diabetes Control and Complications Trial that established the benefits of intensive glycemic control in type 1 diabetes, and the DPP that identified effective treatments to prevent type 2 diabetes. Dr. Shamoon is an elected member of the American Society of Clinical Investigation and the American Association of Physicians.

Shortly after the CTSA Consortium was launched, Dr. Shamoon participated with the other CTSA PIs who formed a new Society for Clinical and Translational Sciences—a collective vision to create a national academic organization that could embrace investigators across the spectrum of biomedical and health research, education and training, and research advocacy. As the various founding organizations came together at their inaugural national meeting a few years ago, it was clear that the ACTS—as it’s now called—would play a unique role on the national stage. The meeting spanned many translational divides, and created an exciting venue for interactions between experts from many scientific disciplines.

Now serving as co-chair for Program Committee for the 2014 meeting, Dr. Shamoon is working with a wide array of junior and senior investigators to build on the successes of the past ACTS conferences in Washington DC. Translational Science 2014 will address the interests of not only early-stage investigators and their mentors, but also provide research leaders at medical schools, academic health centers, and NIH an outstanding opportunity to chart the course for the future in increasingly challenging times.

About ACTS

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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News from ACTS

Save the Date for Translational Science 2014

Mark your calendars for April 9-11, 2014, for Translational Science 2014 at the Omni Shoreham Hotel in Washington, DC. This year’s meeting is set to bring together more than 800 clinical and translational science experts from across the nation to hear from leaders in the scientific field and for cross-disciplinary networking.

Currently, session topics include biostatistics, team science, and academic advancement for translational researchers, among many others. Additionally, the always popular mock study sections and meetings with NIH program officers will return.

Registration and abstract submission will open in October.

Washington Update

As Congress reconvenes following the summer recess, lawmakers face a comprehensive legislative agenda that should keep them quite busy until the end of the year. Beyond immigration reform and other high-profile issues, there are a number of legislative items that Congress must take action on before adjourning. These pressing items include completing appropriations for fiscal year (FY) 2014, raising the debt ceiling, and maintaining reimbursement to physicians for the services they provide to Medicare program beneficiaries.

The Senate has put forward an FY 2014 Labor-Health and Human Services-Education (L-HHS) Appropriations bill that provides a significant funding increase for the National Institutes of Health (NIH). The funding increase for NIH called for by the Senate through the FY 2014 L-HHS Appropriations bill would reverse the funding lost through sequestration and then provide a nominal increase to stimulate new research activities. Thus far, the House of Representatives has not advanced an alternative FY 2014 L-HHS Appropriations measure, and it is unclear if the chamber will do so. At some point though the House and Senate will need to craft a final FY 2014 funding measure, and the clinical and translational research and research training community remains committed to ensuring that this measure includes the Senate’s generous allocations for medical research programs if at all possible.

The Senate can provide meaningful funding increases for federal programs due to the fact that the chamber is operating under a budgetary assumption that automatic across the board funding cuts known as "sequestration" will be cancelled. Presently though, lawmakers have made little progress in the effort to mitigate or avert the sequester despite a growing body of information publicizing its devastating impact on our medical research infrastructure, particularly the training and career development pipeline. There remains a very real possibility that lawmakers will fail to reach agreement on the sequester while also failing to finalize an FY 2014 funding measure, and the clinical and translational research and research training community remains committed to ensuring that this measure includes the Senate’s generous allocations for medical research programs if at all possible.

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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 (satish.raj@vanderbilt.edu) or Dr. Wells.

https://actscience.site-ym.com/?Sept13Connection
Translational Science News

HHS Urged to Take Bigger Role in Trial Consent Process

Patient advocates have called on federal regulators to strengthen the informed consent that research studies require and to increase oversight of the study-recruitment process. Advocates told a panel of experts that patients should better understand the risks and benefits of participating in trials, and that researchers must better explain how a potential trial differs from “standard of care.” The public hearing, held on August 28, came after allegations surrounding the federally funded SUPPORT trial, which focused oxygen saturation targets in 1,316 premature infants. Earlier this year, the watchdog group Public Citizen alleged that the Office for Human Research Protections (OHRP) did not appropriately respond when it uncovered deficiencies in the consent forms and found that many infants’ parents were uninformed about a study’s potential risks. Although babies in the trial reportedly had an increased risk of blindness, brain injury, and death, no consent forms mentioned death as a risk, and 20 of 22 forms did not identify brain injury as a risk. The Department of Health and Human Services then called a public hearing to gather input on developing guidance “regarding what constitutes reasonably foreseeable risk in research involving standard of care interventions such that the risk is required to be disclosed to research subjects.”

From “HHS Urged to Take Bigger Role in Trial Consent Process”
MedPage Today (08/28/13) Pittman, David

Hopkins, U-Md. Await Word on Grant Funding Key in Medical Treatment Discoveries

A funding squeeze in an innovative National Institutes of Health (NIH) grant program is leading to uncertainty for researchers at Johns Hopkins University, the University of Maryland, and other schools in Maryland. Johns Hopkins has received $80 million from the program over the past five years. A Hopkins official has also said that NIH wants Johns Hopkins and other schools to change how they organize their work. “For very large organizations, that is difficult,” said Dr. Daniel Ford, who oversees the grant as vice dean for clinical investigation at Johns Hopkins Medicine. Budget cuts at NIH mean that grant awards will likely be lower than in the past, and traditional NIH grants will also be affected. Dr. Christopher P. Austin, director of NIH’s National Center for Advancing Translational Sciences, which oversees the Clinical and Translational Science Awards, said that the hope is that the success of the clinical and translational research resources will lead to lower costs for all research enterprise with more significant results, such life-saving medicines and treatments. “One of the challenges for us is to figure out how to morph our system,” Austin said. He noted that while research has traditionally been more focused on diagnosing problems, the system needs to learn how to solve those issues.

From “Hopkins, U-Md. Await Word on Grant Funding Key in Medical Treatment Discoveries”
Baltimore Sun (08/16/13) Dance, Scott

‘Lung on a Chip’ Tech Set to Revolutionize Scientific Drug Testing

A new “lung on a chip” is expected to overhaul how scientists test new drugs. The device is intended to provide a faster, less expensive way to develop drugs and avoid animal testing. The technology is a clear polymer chip that replicates the lung’s function and is lined with living human cells inside hollow channels. Donald Ingber, lead researcher and director of the Wyss Institute for Biologically Inspired Engineering at Harvard, said recently that “the cells come from the air sac of the lung and the blood capillaries of the lung. And just like it does in our lung, it actually can mimic whole organ functions.” The chip can also replicate disease processes, such as fluid on the lungs and pulmonary edema. Ingber noted, “We can put bacteria back in and actually mimic infections, and we can actually test drugs for both efficacy and toxicities, so essentially, over time to replace animal testing.” Other organ chips may soon be developed as well, according to Ingber, who said they have federal funding to develop more than 10 different organs, such as the kidney, heart, and gut.

From “‘Lung on a Chip’ Tech Set to Revolutionize Scientific Drug Testing”
CBS News (08/09/13) Cochran, Amanda

Michael J. Fox Foundation CEO: This Is Collaboration in Biology’s Century

In a commentary, Todd Sherer asserts that partnerships are the way to achieve improved treatments and cures for many diseases. Sherer serves as CEO of the Michael J. Fox Foundation for Parkinson’s Research and also sits on the Advisory Council of the National Center for Advancing Translational Sciences. He notes that “Collaboration 2.0” should include unrestricted access to data as found in ADNI (Alzheimer’s Disease Neuroimaging Initiative), which featured the Parkinson’s Progression Marker’s Initiative (PPMI) that was launched in 2010 with 13 industry funding partners. A total of 24 clinical sites are involved in PPMI to collect standardized data and samples from an initial group of 423 PD patients and 196 controls. Crowdsourcing is another key tool to spur engagement with resources, as shown earlier in 2013 with the Parkinson’s Data Challenge, which asked anyone interested to download a set of data that had been collected from PD patients and controls using smartphones. After 630 downloads of the dataset from teams across 21 countries, a prize of $10,000 was awarded to researchers from LiOnSsolver, Inc., who provided proof of concept for a machine learning strategy. Cross-disciplinary collaboration is also crucial as researchers find that treatments for one disease may provide important insights for others. At the recent Alzheimer’s Association International Conference, for instance, researchers discussed new evidence indicating there may be greater overlap in the pathologies of Alzheimer’s and Parkinson’s than previously believed, based on biopsies of patients who were diagnosed with Alzheimer’s but who actually appeared to have dementia caused by Lewy bodies created by high alpha-synuclein accumulation in the brain, which are associated with Parkinson’s.

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Experts: FDA Guidance on Risk-Based Trial Monitoring Most Effective for Phase II, IV

The U.S. Food and Drug Administration (FDA) has finalized guidance on clinical trial oversight, calling for additional remote and targeted risk-based monitoring. The final guidance reviews the key components of the original 2011 draft, discusses risk-based strategies, and clarifies that oversight of trials does not have to be completely performed via on-site monitoring. The agency further notes the “growing consensus that risk-based approaches to monitoring, focused on risks to the most critical data elements and processes necessary to achieve study objectives, are more likely than routine visits to all clinical sites and 100 percent data verification to ensure subject protection and overall study quality.”

Forbes (08/19/13) Sherer, Todd

Understanding Open Science

IOM Report: Patients as Partners in Healthcare

The Institute of Medicine (IOM) recently released a report that calls on the healthcare industry to engage patients as partners, rather than as customers. This could improve both cost savings and quality of care. In February, IOM held a workshop on alterations to the role of the patient in healthcare settings, as part of the IOM’s ongoing roundtable on Value & Science-Driven Health Care. Patients, administrators, and clinicians discussed how to engage with patients, develop better tools to improve patient decisions, and achieve patient data sharing. The report, which covered the workshop, mentioned that there are still significant infrastructural and cultural barriers to changing patients’ role.

TechCocktail (08/15/2013) Kane, Neil

Increasing Minority Participation in Clinical Trials

Three new efforts aim to increase minority participation in clinical trials. Eli Lilly and the Center for Drug Development and Clinical Trials at the Roswell Park Cancer Institute recently announced a program in which they will train 75 to 150 minority oncologists in the conduct of clinical trials. In addition, the Pharmaceutical Research and Manufacturers of America will work with the National Minority Quality Forum and Microsoft to launch the National Clinical Trial Network later this year. The network is an online portal designed to connect communities of patients, practicing physicians, and researchers. Finally, the National Cancer Institute (NCI) is expected to issue a formal funding opportunity announcement seeking applications for funding through the new NCI Community Oncology Research Program (NCORP). In June, the NCI’s Board of Scientific Advisors approved the formal creation of NCORP, which was developed over the past year to consolidate the institute’s Community Clinical Oncology Program (CCOP) Network, which includes minority-based CCOPs across the country and the NCI Community Cancer Centers Program, as well as their research bases.

Genetic Engineering & Biotechnology News (08/13/13) Philippidis, Alex

Report on the White House Lab-to-Market Summit

Earlier this year, the White House Office of Science and Technology Policy (OSTP) and the National Institutes of Health’s Heart, Lung, and Blood Institute organized the White House Lab-to-Market Inter-Agency Summit in Washington, D.C. The meeting intended to ask national experts outside of federal agencies for recommendations to increase the return-on-investment for the $140 billion annual taxpayer expenditure on federally funded research and development. Keynotes were delivered by Tom Kell, deputy director for technology and innovation at OSTP, and Todd Park, U.S. chief technology officer. The speakers challenged panelists to develop inspirational and transformational ideas. Aside from the 20-person expert panel, 60 people from the federal tech transfer machinery industry also came to the summit. Members of the expert panel addressed issues such as common barriers to lab-to-market models, resources that can be leveraged across agencies, mechanisms for sharing best practices, potential linkages with the private sector, and metrics of success. One recommendation by the panel was to create a new Office of Innovation and Federal Technology Partnerships. A second was to strengthen capital investments and entrepreneurial resources to support commercialization of publicly funded research.

Forbes (08/19/13) Sherer, Todd

Understanding Open Science
As technologies for investigating the body increase, including those for genomes, proteins, and metabolites, researchers are also seeing an escalation in organizational models for pharmaceutical companies. However, the time and cost of getting a drug to market continues to be approximately 17 years at a cost of about billion dollars. One approach that should be implemented are collaborations based on standard and shared pre-competitive systems, low transaction costs, openly licensed intellectual property, and significantly increased sample sizes of participants. In the software arena, this methodology is known as "open sourcing," and such an environment is slowly emerging. For instance, U.S. policies on public access to literature and data are enabling researchers to form a wiki of knowledge. New collaboration projects from research reflect an acknowledgement that pre-competitive spaces in biology can actually enhance the power of companies in collaboration. And with access to cheap data for both researchers and lay people, the likelihood of larger sample size increases. At the same time, however, such openness needs to take into account privacy issues, technical infrastructure, policy infrastructure, boundary organizations, and new standards in order to thrive.

From "Understanding Open Science"
Xconomy (08/08/13) Wilbanks, John

Grant Opportunities

NIH, CDC Soliciting Proposals for 2014 SBIR Program

The National Institutes of Health (NIH) is now accepting applications from small businesses looking for funding through the NIH and Centers for Disease Control and Prevention (CDC) Small Business Innovation Research (SBIR) program for 2014. Under the program, Phase I projects are funded with up to $150,000, Phase II projects receive up to $1 million, and Phase III efforts receive funding to help move projects that have already received SBIR funding toward commercialization. Topic areas that NIH and the CDC have identified for applications include a number of therapeutic, biomarker-based, and diagnostic technologies. The National Center for Advancing Translational Sciences (NCATS) plan to fund projects that seek to develop biomarkers for rare diseases that could be used as endpoints for clinical trial measurements. In addition, NCATS is looking for projects that investigate the possible use of CRISPR/CAS systems for genome editing applications. Proposals are due by Nov. 13, 2013. More information is available at Small Business Innovation Research (SBIR) Program Contract Solicitation (PHS 2014-1) Now Available.

From "NIH, CDC Soliciting Proposals for 2014 SBIR Program"
GenomeWeb News (08/29/2013)

NSF: Biotechnology, Biochemical, and Biomass Engineering

The National Science Foundation is offering funding through its Biotechnology, Biochemical, and Biomass Engineering (BBBE) program. The program supports fundamental engineering research that further the understanding of cellular and biomolecular processes, and eventually leads to the development of enabling technology and/or applications in support of the biopharmaceutical, biotechnology, and bioenergy industries, or with applications in health or the environment. Research projects of particular interest to BBBE include metabolic engineering and synthetic biology, quantitative systems biotechnology, tissue engineering and stem cell culture technologies, protein engineering/protein design, and development of novel "omics" tools for biotechnology applications. The average annual award size for the program is $100,000 for individual investigators and $200,000 for multiple investigators. Proposals are due by Oct. 29, 2013.

From "NSF: Biotechnology, Biochemical, and Biomass Engineering"
National Science Foundation (08/22/13)

AAUW: American Dissertation Fellowships

The American Association of University Women is offering funding to help offset a scholar's living expenses while she completes her dissertation. The dissertation fellowship is to be used in the final year of writing the fellowship. Applicants must have completed all of the requisite coursework and passed all the preliminary exams, as well as had the dissertation research proposal or plan approved by Nov. 15, 2013.

From "AAUW: American Dissertation Fellowships"
American Association of University Women (08/22/13)

Rare Diseases Clinical Research Consortia (RDCRC) for Rare Diseases Clinical Research Network (US4)

The National Center for Advancing Translational Sciences (NCATS) has reissued a Funding Opportunity Announcement to support collaborative, multi-site clinical research in rare diseases. The purpose of the cooperative agreement research program is to facilitate clinical research of rare diseases through support for collaborative clinical research in rare diseases, including longitudinal studies of individuals with rare diseases, clinical studies, and/or clinical trials; training of clinical investigators in rare diseases research; pilot/demonstration clinical research projects; and access to information related to rare diseases for basic and clinical researchers, academic and practicing physicians, healthcare professionals, patients, and the lay public. A letter of intent is due by Oct. 7, 2013.

From "Rare Diseases Clinical Research Consortia (RDCRC) for Rare Diseases Clinical Research Network (US4)"
NIH Grants (08/22/13)

NIH Director’s Early Independence Awards (DPS)

The National Institutes of Health, Office of the NIH Director has issued a Funding Opportunity Announcement for the NIH Director’s Early Independence Awards. The
program supports exceptional investigators who wish to pursue independent research directly after completion of their terminal doctoral/research degree or clinical residency, thereby forgoing the traditional post-doctoral training period and speeding their entry into an independent research career. The awards will be for up to $250,000 in direct costs per year, with approximately 10 awards anticipated. Letters of intent are due by Dec. 31, 2013.

From "NIH Director's Early Independence Awards (DP5)"
NIH Grants (08/21/13)

ADD, FMM Collaborate to Advance Translational Research for Mitochondrial Dysfunction

In an effort to further translational research for mitochondrial dysfunction, the Alzheimer's Drug Discover Foundation (ADD) and the Foundation for Mitochondrial Medicine (FMM) are providing grants of up to $200,000 for one-year with potential follow-on funding. The grant includes the discovery and development of new drugs that alter mitochondria function, discovery, and development of novel biomarkers of mitochondria. The grant also places priority on validation of mitochondrial assays for drug discovery and development, and repurposing existing drugs for activities linked to mitochondria function.

From "ADD, FMM Collaborate to Advance Translational Research for Mitochondrial Dysfunction"
Pharmaceutical Business Review (08/19/13)

Diabetes Research Centers (P30)

The National Institute of Diabetes and Digestive and Kidney Diseases has issued a Funding Opportunity Announcement for the Diabetes Research Centers. The centers--formerly named Diabetes Endocrinology Research Centers and Diabetes Research and Training Centers--support three primary research-related activities: research core services, a pilot and feasibility program, and an enrichment program. The institute's Diabetes Research Centers program in 2013 includes 16 Centers located at outstanding research institutions with documented programs of excellence in diabetes-related research. Letters of intent for the Diabetes Research Centers are due by May 17, 2014.

From "Diabetes Research Centers (P30)"
NIH Grants (08/14/13)

NIH Funds Research to Explore a Cell Communication Process

The National Institutes of Health (NIH) will award a total of $17 million this year to 24 research projects to improve scientists' understanding of a recently discovered type of cell-to-cell communication based on extracellular RNA (exRNA). The awards will allow scientists to explore exRNA biology, and develop technologies that will apply the new knowledge to researching, diagnosing, and treating diseases. The awarded research projects will address conditions in which exRNA has a potential role, such as cancers, bone marrow disorders, heart disease, Alzheimer's disease, and multiple sclerosis. Multidisciplinary teams will conduct research in several critical scientific areas. The National Center for Advancing Translational Sciences will administer 18 awards through which researchers will develop exRNA biomarkers and design new ways to use exRNA in treatments. "Expanding our understanding of this emerging scientific field could help us determine the role extracellular RNA plays in health and disease, and unlocking its mysteries may provide our nation's scientists with new tools to better diagnose and treat a wide range of diseases," said NIH Director Dr. Francis S. Collins.

From "NIH Funds Research to Explore a Cell Communication Process"
NIH News (08/13/13)

Creative & Novel Ideas in HIV Research (CNIHR) Program

The Creative & Novel Ideas in HIV Research (CNIHR) program aims to attract early stage investigators from outside the field of HIV research to help address key scientific questions in HIV research. Eligible applicants include junior investigators who have either completed their first terminal research degree, or medical residency within the last 10 years from the concept proposal deadline, and who have a faculty or equivalent position in good standing at an academic institution, or have a comparable position in a not-for-profit organization or institution with a primary mission of research. The awards will be up to two years in length, providing up to $150,000 in direct costs annually. Concept sheets are due by Oct. 16, 2013.

From "Creative & Novel Ideas in HIV Research (CNIHR) Program"
Creative & Novel Ideas in HIV Research (08/08/13)