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March 2014 ACTS Connection

ACTS Connection

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ACTS Leadership Profile: Jasjit S. Ahluwalia, MD, MPH, MS, Board of Directors

Dr. Ahluwalia has devoted the past 22 years to improving the health of high risk populations particularly underserved and ethnic minorities. His training is in Internal Medicine with a Master's in Public Health and a Master's in Health Policy. At Harvard, he also did a Clinical Epidemiology Fellowship which provided the foundational training he needed for my career. He was first a faculty member at Emory University Medical School and School of Public Health and in 1997 joined the University of Kansas where he went on to become the Sosland Family Professor and Chair of the Department of Preventive Medicine and Public Health. In 2005, Dr. Ahluwalia was recruited as the founding Director for the Office of Clinical Research at the University of Minnesota. This served as the precursor to what then became the Clinical and Translational Sciences Institute (CTSI) which is funded by a CTSA award. For his CTSI, Dr. Ahluwalia serves as Associate Director and directs the clinical research training, education, and career development activities. In summer 2009, he received the NIH Comprehensive Centers of Excellence in Health Disparities and Minority Health award and established the Center for Health Equity for which he serves as the founding Executive Director. His main research area is in nicotine addiction and smoking cessation in African Americans. His group has conducted clinical trials, large data set analysis, and qualitative research in this area, and have collaborated with others on pharmacogenetics and cancer biomarkers. They continue to publish about 20 papers a year. During his professional career, Dr. Ahluwalia has been the PI on about \$20 million in funding and had over \$80 million as a co-investigator. He currently serves as the Chair of the National Advisory Council for the National Institute of Minority Health and Health Disparities. He is on the Board of the Directors of the Association for Clinical and Translational Sciences and has been active in the organization since its inception. He came to the Board having served on the Board of Directors for the Association for Clinical Research Training (ACRT) from 2009 and 2013. He was asked to continue his efforts with the new organization, ACTS, and very enthusiastically agreed to do so.



What is your current position on the board? Please describe your vision/goals for your ACTS committee and the association as a whole.

I have served on the Board of the Association of Clinical and Translational Sciences since January 2013 when it was officially formed. My vision for ACTS is that it should be the leading organization and national meeting for clinical and translational research that is non-disease specific. As we move into an era of team science and solving complex clinical and population health issues, it is imperative that we leverage the different disciplines to come up with innovative solutions. In addition, we must ensure a strong future by training the next generation of clinical and translational investigators. Related to this, it is imperative that we remain committed to, and take efforts to have a diverse biomedical workforce. This is a high priority for NIH and should be one for our organization.

Tell us about a career accomplishment and its impact on translational science.

The career accomplishments that I view as most important to me are related to mentoring. It gives me no greater pleasure than to see a trainee, be it a student, postdoctoral fellow, or junior faculty, for whom I have served in some ways a mentor, be successful with either a manuscript, a national presentation, a grant, or a new faculty position. Related to my own work, I feel that the past 20 years focusing on African American smokers, we have made a big difference in better understanding how metabolism, genetics, racism, and the social determinants of health impact the initiation of smoking, the maintenance of smoking, the difficulty in quitting, and also understanding the genetics and metabolism of nicotine and cancer biomarkers among African Americans. The impact on translational science has been gratifying. It has impacted policy with regards to indoor air smoking laws, reimbursement of smoking cessation medications, coverage for smoking cessation counseling and medications through government programs such as Medicaid and the VA, and has empowered communities to take an activist role on their own health as it relates to smoking.

What or who influences your work in translational science?

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I am most inspired by my mentees, and the population that I have worked with. They have challenged me to work harder and smarter to help answer very tough questions. In addition, I have been fortunate to work with a network of colleagues from many different disciplines like pharmacogenetics, sociology, anthropology, biochemistry and others. Working in such inter-disciplinary teams with so many different perspectives on each problem has influenced both my own approach to these issues and also allowed us to think out of the box.

How do you use the Translational Science Meeting to support your career and why should others consider attending the meeting?

Besides my commitment to the annual Translational Science Meeting both as a participant and as a Board of Directors member, I find the meeting inspiring, motivating, and friendly. Two of the past three meetings, I have had the privilege to present a workshop with colleagues. One of the main benefits for me is the opportunity for networking, and I find the meeting very productive and enjoyable as I get to know an increasing number of members. It is a meeting that I very much look forward to every year. I would encourage those interested in being a leader in their respective field or those who really are inspired to make a big difference to take this meeting seriously, to get involved, and to help shape the organization.

How do you suggest other members receive maximum value from ACTS?

It's very important for members to understand that this is their organization and only as helpful as the effort they put into it. It is important that they remain active on the listserv, volunteer as an abstract reviewer, and volunteer to serve on committees. The annual meeting will be successful and valuable when members submit abstracts, workshops and symposiums and actively attend and participate in sessions. Most importantly, I believe that members should take advantage of the networking opportunities that occur at the meeting. I suggest for networking effectively, being bold and going up to people you don't know and introducing yourself. Such conversations have always had pivotal importance in my career.

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News from ACTS

Translational Science 2014: Online Registration Closes Soon!

We're less than **two weeks** away from Translational Science 2014! Be part of the year's premier research meeting – **register today** and join more than 700 of your peers April 9-11 in Washington, D.C. for three days of networking and education. At this event, you will also have the opportunity to view over 450 abstracts of outstanding research in the field. Connect with leaders and peers to learn and share best practices, and go back to your lab with new ideas and strategies to take your research even further!

For more information and program details, visit www.translationalsciencemeeting.org.

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Washington Update

On Capitol Hill, March came in like a lamb despite the release of the President's fiscal year (FY) 2015 budget request to the Congress. Typically, this event would signify the beginning of the annual appropriations process and kick off contentious partisan battles over funding-levels and spending-priorities. However, since the FY 2015 budget limit was already agreed as a component of the FY 2014 omnibus package, the President's FY 2015 request is largely a symbolic and political document.

That being said, the FY 2015 budget request does call for increased funding for medical research and patient care programs. Specifically, the Administration recommends increasing the budget for the National Center for Advancing Translational Sciences (NCATS) by \$25 million to \$657 million. Unfortunately, the request also calls for cutting NCATS' flagship program, the Clinical and Translational Science Awards (CTSA) by \$3 million in FY 2015. Other programs of interest received the following recommendations through the FY 2015 budget request:

- \$30.4 billion program level for the National Institutes of Health (NIH), an increase of \$211 million over FY 2014
- \$10.75 billion program level for the Health Resources and Services

Administration (HRSA), an increase of \$1.8 billion over FY 2014.

- \$440 million program level for the Agency for Healthcare Research and Quality (AHRQ) a decrease of \$24 million from FY 2014.

With the budget-levels previously set, Congress has been working since the beginning of the year to craft the FY 2015 appropriations bills that will fund NCATS, CTSAs, and all other federal programs. The President's budget request is just one example of input that legislators will consider when deciding funding levels for clinical and translational research and research training program. These legislators want to hear from you, their constituents, as they make these decisions and they need to understand the importance of providing meaningful funding increases that support the full spectrum of research in FY 2015.

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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

Rare Diseases in Children Pose Unique Challenges

The Food and Drug Administration (FDA) is focusing on pediatric diseases in recognition of International Rare Disease Day on Feb. 28, 2014. Rare diseases tend to be genetic in origin and thus disproportionately affect children. Creating drugs and devices for children poses a number of challenges and unique considerations, and their development continues to lag, writes Dr. Gayatri R. Rao, director of FDA's Office of Orphan Products Development (OOPD). Congress responded by directing the FDA to issue a report and strategic plan for accelerating the development of therapies for pediatric rare diseases. In a series of public meetings held by the FDA in January, there emerged a couple of common themes: the importance of patient advocacy groups in furthering drug development, and the need for strong collaborations among patients, researchers, industry, and government. The OOPD is coordinating an effort with Center for Drugs Evaluation and Research (CDER), the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, and the Office of Pediatric Therapeutics to develop a report and plan to encourage the development of therapies for pediatric rare diseases. OOPD is also collaborating with CDER to launch a Web-based educational tool on rare diseases for patients, advocacy groups, researchers, and industry.

From "Rare Diseases in Children Pose Unique Challenges"
FDA Voice blog (02/27/14) Rao, Gayatri R.

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American Heart Association Launches Accelerator to Find Internal Game Changers

Dr. Ross Tonkens, a cardiologist and chief medical officer in Cary, N.C., has directed the creation of the Science and Technology Accelerator Program within the American Heart Association (AHA) to target and support new ideas. Seeking to redefine what an accelerator program can look like in healthcare, the board of the AHA and various affiliates are partnering to host forums and fundraisers to gather investment and support. The AHA's 2020 Impact Goals are to reduce deaths from cardiovascular disease and stroke by 20 percent and improve Americans' cardiovascular health by 20 percent. The accelerator program, which is focused on identifying game-changing technology and research that can be brought to market as quickly as possible, may help to achieve those goals. The AHA Science and Technology Accelerator Program invests expertise in areas such as scientific research, regulatory issues, intellectual property, and commercialization strategies, seeking to ensure that all ideas, even those from younger AHA participants, are solicited, considered, and implemented to the best of their abilities.

From "American Heart Association Launches Accelerator to Find Internal Game Changers"
Forbes (02/27/14) Fisher, Nicole

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A White House Call to Action to Advance the BRAIN Initiative

President Obama introduced the BRAIN (Brain Research through Advancing Neurotechnologies) Initiative last year to encourage the development and application of scientific breakthroughs that further the understanding of brain function and its relationship to behavior. The initiative is supported by federal agencies including the Defense Advanced Research Projects Agency, the National Institutes of Health, and the National Science Foundation. The president has called for the BRAIN Initiative to be "all hands on deck," involving the government as well as companies, health systems, patient advocacy groups, philanthropists, state governments, research universities, private research institutes, and scientific societies. The White House will hold an event later this year that will feature these group's role in attaining the president's objective on this project. Such commitments include basic and translational research at universities and private research institutes; involve patient advocacy organizations in accelerating the development of diagnostics, treatments and cures; and develop information technology infrastructure to improve researchers' abilities to store, share, visualize, and analyze huge volumes of data to be generated by the BRAIN initiative. Other goals include encouraging pre-competitive collaborations with industry; creating education and training programs to prepare the next generation of scientists, engineers, and entrepreneurs; and developing regional "clusters" to accelerate economic growth, job creation, and innovation in the commercial neurotechnology domains.

From "A White House Call to Action to Advance the BRAIN Initiative"
White House Blog (02/24/14) Kalil, Tom

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New Effort Links Research, Better Health Care

The Delaware Center for Translational Research, also known as ACCEL, is bringing together researchers from the University of Delaware (UD), Nemours/Alfred I. duPont Hospital for Children, Christiana Care Health System, and the Medical University of South Carolina. ACCEL's goal is to develop a research pipeline to deliver the latest scientific research to health providers and other clinical practices. ACCEL was created through a five-year, \$20 million grant from the National Institutes of Health (NIH), along with \$5 million in funding from the state of Delaware and \$3.3 million in matching funds from the participating organizations. The NIH grant seeks to expand capacity for research while encouraging additional research funding in the future through investment, says Stuart Binder-MacLeod, associate vice provost for clinical research at UD. Specifically, the funding will enable such things as mentoring, recruitment of new investigators, and the development of a community outreach and engagement program encompassing the work done in labs and clinician offices, including basic science, clinical, and translational research. Under ACCEL, participating organizations also will conduct smaller pilot programs focusing on population health issues that need additional attention, such as childhood obesity, infant mortality, cancer, cardiovascular disease and stroke.

From "New Effort Links Research, Better Health Care"
Delaware News Journal (02/18/14) Bothum, Kelly

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Dispute Over the Future of Basic Research in Canada

Last year, the Canadian government announced that the National Research Council, which has focused largely on basic research, would be converted into a "concierge service" to encourage technological innovation by industry and generate high-quality jobs. The decision launched a dispute over Canada's capacity to conduct fundamental research and found university scientists and academic organizations speaking out against the government's preference for commercially applicable science. This remodeling is part of a series of policy changes in recent years that have earned strong criticism among Canadian academics. Charles Drouin, a spokesman for the National Research Council, says that the agency is not moving away from supporting fundamental research but is better concentrating its efforts. The Natural Sciences and Engineering Research Council, a federal granting agency that finances Canadian scientists, is another battleground for the future of basic research. In 2011-2012, its "discovery" grants for fundamental research accounted for 38.4 percent of its budget, down from 50.1 percent in 2001-2002. At the same time, its "innovation" grants that encourage the transfer of university-developed technology to industry rose from 25.3 percent to 31.4 percent of its budget.

From "Dispute Over the Future of Basic Research in Canada"
New York Times (02/17/14) Birchard, Karen; Lewington, Jennifer

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Researchers Hope New Data Collaborative Will Lower Health Care Costs, Improve Treatment

A new program called the Greater Plains Collaborative will connect 10 health centers in seven states. The program, part of the Patient-Centered Clinical Research Network (PCORnet), seeks to assist patients and their caregivers in making more informed choices. The network includes Marshfield Clinic, the Medical College of Wisconsin, and the University of Wisconsin School of Medicine and Public Health. "Instead of trying out treatments that may not work for you and then trying out other treatments and other treatments, and going down that kind of path, we'll be able to select the right treatment for you from the beginning," explains Murray Brilliant, director of human genetics at Marshfield Clinic Research Foundation. The Patient-Centered Outcomes Research Institute is investing more than \$100 million in developing PCORnet. The Greater Plains Collaborative increases by 6 million the number of active patients whose medical data will be available to each institution.

From "Researchers Hope New Data Collaborative Will Lower Health Care Costs, Improve Treatment"
WSAW (02/09/14) Anderson, Hannah

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Scientist's Experiment in Fundraising

An increasing number of researchers are turning to crowdfunding Web sites to secure funds for such things as gathering data or testing new ideas. These sites include RocketHub, Experiment, Indiegogo, and SciFund Challenge, where funders range from consumers to investors. Ethan O. Perlstein hopes to secure \$1.5 million to set up his own lab through a site called AngelList. His planned Perlstein Lab would focus on finding drugs to treat lysosomal storage diseases, in which cells are unable to produce and recycle waste. Margaret Anderson, executive director of FasterCures, which seeks to accelerate the development of drugs, is concerned that some people who contribute through crowdfunding may lack a thorough understanding of science and could end up supporting scientifically questionable research. FasterCures has developed a set of questions to help guide people prior to donating money, which could be used for crowdfunded projects well, Anderson says. Linda Avey, a sciences-focused entrepreneur, believes crowdsourced research can succeed if the science is sufficiently discussed with the public in order to "break down the barriers between ivory-tower research and the average citizen."

From "Scientist's Experiment in Fundraising"
Wall Street Journal (02/05/14) Marcus, Amy Dockser

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NIH Announces Novel Venture With Drug Companies to Fight Major Diseases

As part of the Accelerating Medicines Partnership initiative, the National Institutes of Health (NIH) has announced pilot projects targeting Alzheimer's disease, type 2 diabetes, rheumatoid arthritis, and lupus. The federal government and nonprofit organizations will be working with private industry to accelerate the search for treatments, which will include the cooperation of scientists from 10 entities as well as the sharing of data, blood samples, and tissue specimens. The partnership is the product of two years of negotiations between officials at NIH and drug companies.

Researchers hope to successfully go through a very large data set of opportunities to find and test new biomarkers for disease. The first phase of the project will be focused primarily on collaborations between the industry and NIH, says Robert Clarke, dean of research at Georgetown University Medical Center. The first group of projects will last three years to five years and will involve an investment of more than \$230 million from companies including Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Eli Lilly, Merck, Pfizer, Sanofi, and Takeda. Participating pharmaceutical companies say they will not launch commercial ventures based on discoveries from the partnership until after the data has been made publicly available.

From "NIH Announces Novel Venture With Drug Companies to Fight Major Diseases"
Washington Post (02/04/14) Cha, Ariana Eunjung

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Screening Platform Is a Launch Pad for Novel Treatment Combinations

The National Center for Advancing Translational Sciences (NCATS) is committed to developing solutions to healthcare challenges, such as choosing combination therapies for patients with diseases such as cancer or tuberculosis. NCATS investigators recently developed a sophisticated combination drug screening platform that allows clinicians to narrow down a list of potential drug combinations to find those most likely to help patients. Investigators used a particular variety of diffuse large B-cell lymphoma for the study. A multidisciplinary team developed a high-capacity robotic platform to screen drug combinations, doing in a couple of days what human researchers would take months to complete. The system performs automated assays using groups of diseased cells that are each treated with a unique drug combination. The assays then reveal the effects on each group of cells. The platform uses a drug library called the Mechanism Interrogation PlatE, which contains drugs that are relevant for clinical use in cancer. With this research, NCATS provides the broader scientific community with access to the control software and data necessary to build off the initial work. The collaborators used the new platform to speed up the search for a compound to combine with the new drug ibrutinib, approved to treat two different forms of lymphoma. The National Cancer Institute hopes to integrate the new screening platform into more of its research, and it is collaborating with NCATS on combination drug screening projects that involve cancers of the kidney, pancreas, and ovaries.

From "Screening Platform Is a Launch Pad for Novel Treatment Combinations"
National Center for Advancing Translational Sciences (02/01/2014)

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Grant Opportunities

NCATS Seeks Ph.D. Candidate for Alpha-1 Project Fellowship

The National Center for Advancing Translational Sciences (NCATS) is accepting applications for a two-year postdoctoral fellowship position funded by the Alpha-1 Project. The Alpha-1 Project is the philanthropic arm of the Alpha-1 Foundation, which aims to help people affected by the rare genetic condition in which the body does not circulate enough of a protein that protects the lungs from damage. Qualified applicants for the fellowship must hold a Ph.D. in chemical, molecular, or cellular biology. The selected individual will work with drug discovery and development experts in the assay development screening technology laboratory in NCATS' Division of Pre-Clinical Innovation, and he or she will receive training in assay development, screening techniques, and data analysis to become equipped to lead a translational research project. Applications are due by May 5, 2014.

From "NCATS Seeks Ph.D. Candidate for Alpha-1 Project Fellowship"
National Center for Advancing Translational Sciences -- Newsletter (02/20/2014)

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Empirical Research on Ethical Issues Related to Central IRBs and Consent for Research Using Clinical Records and Data (R01)

The National Institutes of Health (NIH) has issued a funding opportunity announcement (FOA) in an effort to encourage empirical research on ethical issues related to central Institutional Review Boards (IRBs) and consent for research using clinical records and data. Central IRBs have been used in some contexts, but additional research and analysis could lead to wider use of central IRBs. Also, with the increasing digitization and interoperability of clinical records, there are new opportunities for research involving clinical records and data raise a number of issues, including privacy, confidentiality, and informed consent. NIH plans to fund three to five awards for this FOA in fiscal year 2014, for a total of \$1.3 million. Applications are due by April 18, 2014.

From "Empirical Research on Ethical Issues Related to Central IRBs and Consent for Research Using Clinical Records and Data (R01)"
NIH Grants (02/20/14)

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PCORI Announces \$15.5 Million for Engagement Awards Program

The Patient-Centered Outcomes Research Institute (PCORI) has unveiled the \$15.5 million Eugene Washington PCORI Engagement Awards program, aimed at creating opportunities for patients and other stakeholder communities to become more involved in patient-centered outcomes research (PCOR). PCORI will support engagement projects in three categories: knowledge, training and development, and dissemination. Specifically, Knowledge Awards will be bestowed to build knowledge around how consumers of healthcare information receive and make use of PCOR findings. Training and Development Awards will promote the training and development of the "non-usual suspects" and others from the patient and stakeholder community to increase capacity for engaging in PCOR, while Dissemination Awards will strengthen the groundwork for disseminating and implementing the findings of PCORI funded research into practice. Proposals will be evaluated and awarded on a rolling basis. Each award provides up to \$250,000 for a project whose duration should not exceed two years.

From "PCORI Announces \$15.5 Million for Engagement Awards Program"
Patient-Centered Outcomes Research Institute (02/13/2014)

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DHHS: Announcement of Availability of Funds for Teenage Pregnancy Prevention: Research and Demonstration Programs (Tier 2)--Community Collaborative

The Department of Health and Human Services has announced funding for teenage pregnancy prevention. The purpose of the funding is to work with three to five communities with high teen pregnancy rates to develop new strategies for preventing teen pregnancy in groups and areas with demonstrated need. The award recipient will be expected to bring together a team in each selected community made up of representatives from various sectors to develop a strategy or prevention framework to address teen pregnancy prevention in their individual community. Applications are due by April 24, 2014.

From "DHHS: Announcement of Availability of Funds for Teenage Pregnancy Prevention: Research and Demonstration Programs (Tier 2)--Community Collaborative" *Grants.gov (02/07/14)*

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CHF: Research in Congenital Heart Disease

The Children's Heart Foundation (CHF) is accepting proposals for clinical research projects related to congenital heart disease. Projects should help CHF fulfill its mission of supporting research toward discovering the cause and improving the methods for diagnosing, treating, and preventing congenital heart defects. The grants will be for up to \$100,000 per year for a maximum of two years. Research proposals must be submitted by June 6, 2014. CHF's Medical Advisory Board will review the proposals by late fall 2014, and those recommended will receive funding in December 2014.

From "CHF: Research in Congenital Heart Disease" *Children's Heart Foundation (02/01/2014)*

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