Present at the Translational Science 2014 Meeting: Submit an Abstract by January 29

Share your research or encourage someone you know to submit their work and present at Translational Science 2014, taking place April 9-11, 2014 in Washington, DC and sponsored by the Association for Clinical and Translational Science (ACTS) and the American Federation for Medical Research (AFMR). New this year, in addition to various poster sessions, a limited number of abstracts will be selected for oral presentations.

Abstracts may be submitted in the following categories:

- **T0: Basic Scientific Discovery** - Preclinical or "bench" research directed at mechanisms and presentations of human disease
- **T1: Translation to Humans** - Testing basic science discoveries for clinical effect and/or applicability
- **T2: Translation to Patients** - Testing new interventions in human subjects under controlled environments to form the basis for clinical applications and evidence-based guidelines
- **T3: Translation to Practice** - Research on the application of new interventions or therapies in general practice; research that yields knowledge on best ways to implement new medical interventions in the clinic
- **T4: Translation to Population** - Investigations of factors and/or interventions that influence the health of populations

We look forward to seeing you at Translational Science 2014! Early-Bird registration rates are only available until February 28, so click the button below and register today!

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News from ACTS

2014 Translational Science Awards: Call For Nominations Now Open!
Deadline: February 7, 2014

Do you know a member of the Translational Science community that has gone above and beyond in their contributions to the field over the last year? If you answered yes, then make a nomination for one of the following awards!

ACTS Distinguished Investigator Awards
The ACTS Distinguished Investigator Awards recognize senior investigators whose innovative research or education leadership has had a major impact on clinical and translational science.
The three Distinguished Investigator Awards include:
- Translation from bench research to patient application – the Edward H. Ahrens, Jr. Award for Patient-Oriented Research
- Translation from early clinical use to applicability for widespread clinical practice
- Translation from clinical use into public benefit and policy

ACTS Distinguished Educator Award
This award recognizes a clinical investigator who has distinguished him or herself as a mentor and leader.
Recipients of this award are innovators of clinical research training program, successful mentors who have documented national leadership in clinical research education programs, issues and funding.

AFMR Outstanding Investigator Award
The Outstanding Investigator Award is presented annually to an investigator age 45 or younger in recognition of excellence in biomedical research. Recipients of this award have provided innovative insight and had significant impact on a major scientific or clinical problem and demonstrated intellectual and scientific independence.

Click here to view the 2014 ACTS Distinguished Investigator, ACTS Distinguished Educator, and AFMR Outstanding Investigator Awards Nomination Form

Team Science Award
This award was established to acknowledge and catalyze the growing importance of interdisciplinary teams to the translation of research discoveries into clinical applications and eventually widespread clinical practice. Proactive interaction between academic and industry researchers is particularly crucial to continue progress and accelerate drug development. Recipients have demonstrated their support of a team science environment by creating mechanisms to enhance the required infrastructure, such as through pilot funding, technology transfer offices, shared resources, etc., and by presenting awards, honors, appointments, and promotions to those who participate in interdisciplinary teams.

Click here to view the 2014 Team Science Award Nomination Form

Call for Nominations - Translational Science 2014 Trainee Travel Awards

Members are invited to nominate one trainee for the Burroughs-Wellcome Fund Trainee Travel Award to attend the Translational Science 2014 Meeting on April 9-11, 2014 in Washington, DC. This includes complimentary registration to the meeting, and up to $600 of travel costs.

Trainees will benefit from special sessions designed with them in mind, including "Meetings with Program Officers," poster sessions, and networking opportunities. Details of the full program are available on the meeting program page.

Nominations must be submitted by February 7, 2014.

Please include:
- The nominee's CV
- The name, degree(s), and training status of the nominee (e.g., enrolled in clinical research Master's or K30 program, K12, K23, R25 or other career development award)
- A paragraph or two (no more than one page) about the current status and career development plans of the nominee
- A statement of commitment to cover any remaining travel expenses for their trainee.

Washington Update

The Second Session of the 113th Congress began with legislators restoring a sense of optimism to the annual budget and appropriations process. At the end of the last year, Congress passed and the President signed the Bipartisan Budget Act of 2013. The legislation established an overall Fiscal Year (FY) 2014 federal spending level of $1.012 trillion. This spending level is a compromise between the $967 billion level previously proposed and the $1.086 trillion spending level that the Senate had been advocating for.

By authorizing additional funding through the Bipartisan Budget Act, Congress effectively cancelled the 2.1% sequester that discretionary medical research and patient care cut that were scheduled to take in mid-January. The additional funding provided by the legislation also restored a portion of the 5% funding cut that discretionary medical research and patient care programs took through sequestration in FY 2013. Despite the increased resources available to mitigate the impact of sequestration on discretionary medical research and patient care programs, no relief has been provided to the 2% cut that Medicare has taken as a result of the sequester.

With the FY 2014 budget level set, Congress worked quickly to craft and enact an omnibus appropriations package that included the twelve annual appropriations bills which fund all federal programs. As a result of the tireless outreach of dedicated advocates, the Labor-Health and Human Services-Education Appropriations bill that funds the National Institutes of Health and similar programs, fared well through the omnibus package. Overall, funding for NIH was increased by nearly $800 million to $29.9 billion in FY 2014. Clinical and translational research programs also saw meaningful increases to their budgets. The Clinical and Translational Science Awards (CTSA) program saw a sizable funding increase of approximately $40 million, which brought the programs budget up to $478.75 million, while the FY2013 post-sequestration level of about $425 million. The joint explanatory statement accompanying the omnibus package includes the following language on the CTSA program:

Clinical and Translational Science Awards (CTSA): The agreement provides a specific funding level for the core CTSA program within the NCATS statutory language. This change removes the funding flexibility provided during the establishment years of NCATS. The ICs are expected to continue to use and provide support to the CTSA infrastructure for clinical trials and other scientifically appropriate activity. In addition, NCATS should continue to collaborate with all ICs on the overall CTSA program. The 2013 Institute of Medicine (IOM) report recommends the development of a comprehensive strategic plan with measurable objectives. The NCATS is expected to move forward with implementing the IOM recommendations in...
consultation with the CTSA community. Any significant changes to the program should be done with transparent and ongoing consultation with the CTSA community and NIH ICs. NCATS shall provide an update in the fiscal year 2015 budget request of all planned and expected changes since the release of the IOM report through fiscal year 2015 to include a specific plan on how NCATS will communicate and coordinate with the CTSA community.

The ACTS Connection Editors Want Your Feedback
ACTS Connection Editor, Dr. Satish R. Raj, MD, MSCI, and Associate Editor, Dr. Quinn Wells, MD, PhPhD, 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.

Translational Science News

Genezyme, NORD Establish Program to Help Undiagnosed Patients with Rare Diseases

Genezyme and the National Organization for Rare Disorders (NORD) have set up a fund to help finance standard diagnostic testing for people with mysterious, undiagnosed medical conditions. The fund will be used for patients who applied to the National Institutes of Health Undiagnosed Diseases Program but who cannot afford medical tests needed to make them eligible to participate in the program. The program will expand in 2014 to include major academic medical institutions throughout the United States, and the fund will be available to patients at all of the clinical sites. “While progress in scientific research has been very promising in recent years, millions of Americans who have rare diseases go for five years or longer without an accurate diagnosis. This delay’s treatment and creates enormous financial and emotional stress for patients and their families,” said NORD president and CEO Peter Saltonstall.

From "Genezyme, NORD Establish Program to Help Undiagnosed Patients with Rare Diseases’’
PharmaAlli.com (12/18/13)

PCORNet: Meeting Clinical Trials’ Need for Speed

The Patient-Centered Outcomes Research Institute (PCORI) has announced the launch of a new data-sharing network called the NOILNer). PCORNet will consist of Clinical Data Research Networks (CDRNs) and Patient-Powered Research Networks (PPRNs). CDRNs are made up of healthcare groups such as academic health centers, community hospitals, and health plans that use electronic medical records to build patient databases and a clinical trial infrastructure that can be accessed by researchers from many different organizations while safeguarding patient privacy and confidentiality. PPRNs, meanwhile, are patient-oriented groups linked by certain diseases or conditions. Successful groups will receive support from PCORNet, and will be responsible for outreach, expanding networks of patients, and gathering standard patient data.

From “PCORNet: Meeting Clinical Trials’ Need for Speed’’
NIH Director’s Blog (12/17/13) Collen, Francis

PCORI Approves $191 Million to Support Patient-Centered Comparative Effectiveness Research

The Patient-Centered Outcomes Research Institute (PCORI) has designated $97.5 million in new funding for 33 comparative-effectiveness research (CER) studies intended to answer questions important to patients and those who care for them. In addition, PCORI has approved $93.5 million to build and upgrade the research data network called the NOILNer). PCORNet will consist of Clinical Data Research Networks (CDRNs) and Patient-Powered Research Networks (PPRNs). CDRNs are made up of healthcare groups such as academic health centers, community hospitals, and health plans that use electronic medical records to build patient databases and a clinical trial infrastructure that can be accessed by researchers from many different organizations while safeguarding patient privacy and confidentiality. PPRNs, meanwhile, are patient-oriented groups linked by certain diseases or conditions. Successful groups will receive support from PCORNet, and will be responsible for outreach, expanding networks of patients, and gathering standard patient data.

From “PCORI Approves $191 Million to Support Patient-Centered Comparative Effectiveness Research’’
Patient-Centered Outcomes Research Institute (12/17/13)

NIH Program Bridges Gap to Develop New Therapeutics

The National Institutes of Health (NIH) has initiated three pre-clinical projects intended to promote new treatments for acute radiation syndrome, brain injury following cardiac arrest, and a rare blood disorder. The projects are part of the Bridging Interventional Development Gaps (BrIDGes) program, which is funded by the NIH Common Fund and led by the National Center for Advancing Translational Sciences (NCATS). The BrIDGes program allows for access to scientific and clinical research tools and resources for pre-clinical therapeutic development. BrIDGes researchers and partner scientists work together to bridge the gap between a basic discovery and early-onset testing, thereby ensuring potential treatments have a chance to reach patients who need them,” said Dr. Christopher Austin, NCATS director. The three projects selected from the 2013 application solicitation are Manufacturing of BLIP76-LyoPL for Acute Radiation Syndrome, The Development of Minihepcidins for the Treatment of Beta Thalassemia, and HBN-1 Regulated Hypothermia Formulation and discovery and clinical testing, thereby ensuring potential treatments have a chance to reach patients who need them.”

From "NIH Program Bridges Gap to Develop New Therapeutics’’
NIH News (12/17/13)

Building Support for Basic Research

At the recent American Society for Cell Biology (ASCB) meeting, life scientists discussed the growing push toward translational research. Part of this trend has been prompted by smaller federal science budgets. Additionally, said ASCB President Don Cleveland, “In part, this idea that translation, translation, translation, everything has to have direct translation, was driven by us—we the scientists, those sitting on review panels.” Georgia Tech Deputy Director for Academic Affairs and Deputy director of the National Institute of Diabetes and Digestive and Kidney Diseases said that, “One of the challenges is...in peer review. I think there has been a misunderstanding of what it means to say ‘significance’ of the work. People think that means we must emphasize the clinical [or] translational aspects, rather than the fact that something is ‘significant’ for other reasons, such as advancing scientists' understanding of basic biological processes.” Germino said that peer reviewers who sit on study sections should define the importance of proposals for translational research projects. “That would really go a long way to helping make sure that [basic] R01s are funded.”

From “Building Support for Basic Research’’
The Scientist (12/24/13) Forme, Tracy

Using platforms the size of a thumb drive, U.S. researchers have begun working on creating human tissue from stem cells and manipulating them to replicate functions of human organs. The research is known as “human-on-a-chip,” and scientists say it could be a breakthrough for medical treatment. While the chips do not contain human organs, they do hold tissue that can copy a working heart, liver, or lung. The scientists use 3-D printers to build the organs. “This technology would be able to take tissue from an individual and basically reprogram it so it’s representing all of the major organ systems, so you could essentially have a mini personalized human-on-a-chip so that you can really get an idea of what a response would be for an individual with a toxin or a drug, or whatever you’d like to test,” says Krzem Fehru, tissue chip program manager of the National Center for Advancing Translational Sciences (NCATS).

From “Human-on-a-Chip’’
Nature Biotechnology (12/21/13) O’Connell, Kate

NIH Data-Sharing May Advance Genetic and Translational Research, Therapeutic Target Discovery

https://actscience.site-ym.com/?page=January14Connection

3/5
Comprehensive information on the biochemical components of small interfering RNA (siRNA) molecules is now available publicly for the first time. These molecules are used in research to assist scientists in better understanding how genes function in disease. The National Center for Advancing Translational Sciences (NCATS) worked with Life Technologies Corporation, which owns the siRNA information, to make it available to all researchers. The siRNA molecules can selectively inhibit the activity of genes, and are used in research on RNA interference (RNAi). A team of scientists led by Richard Youle at the National Institute of Neurological Disorders and Stroke and Scott Martin at NCATS recently used RNAi to find genes linked to Parkinson's disease, potentially leading to new starting points for developing treatments. NCATS and Life Technologies are offering access to siRNA data from Life Technologies' Silencer Select siRNA library, which includes 65,000 siRNA sequences targeting more than 20,000 human genes. NCATS is also releasing complementary data on the effects of each siRNA molecule on biological functions. The public can access all of this at no cost via NIH's public database, PubChem.

From "NIH Data-Sharing May Advance Genetic and Translational Research, Therapeutic Target Discovery"

News-Medical.Net (12/12/13)

GSK Forms Oncology Clinical and Translational Consortium

GlaxoSmithKline (GSK) has established a collaborative scientific research network involving comprehensive cancer centers around the world. The Oncology Clinical and Translational Consortium (OCTC) includes Gustave Roussy in France, the University of Texas MD Anderson Cancer Center, Memorial Sloan-Kettering Cancer Center, Massachusetts General Hospital in New York, Netherlands Cancer Institute in the Netherlands, Princess Margaret Cancer Centre in Toronto, University Health Network in Canada, and Vall d'Hebron Institute of Oncology in Spain. GSK hopes to gain the group's expertise in preclinical, translational, and clinical development of novel anticancer therapeutics, while OCTC members have access to studies with the drug company's early stage oncology pipeline and opportunities to advance the next generation of novel oncology therapeutics. According to GSK, oncology R&D Head Rafael Amado, "The consortium, together with GSK, will design and execute research programs in a focused and expedited way, allowing us to potentially develop new diagnostic tools and medicines to better treat cancer patients."

From "GSK Forms Oncology Clinical and Translational Consortium"

Pharmaceutical Business Review (12/08/13)

The Growing Need for Outcome Studies and the Impact on R&D Costs

In recent years, long term studies designed to assess the effect of drugs on disease outcomes have provided unexpected results. The role of niacin, for instance, was challenged after long-term trials indicated that statins worked better for raising HDL cholesterol and lowering LDL cholesterol. Meanwhile, a trial published in the New England Journal of Medicine focusing on "A NEPHRONE," revealed that combining lisinopril and losartan was associated with an increased risk of adverse events, such as hyperkalemia and kidney failure, in people with end-stage renal disease. An accompanying editorial noted that "when either approved or off-label drug use is guided by changes in surrogate markers without proof from hard-outcomes trials, problems may occur." This points to an increasing need for hard-outcomes trial information, especially in areas where longstanding treatments already exist. An official at the U.S. Food and Drug Administration recently announced that a new class of LDL-lowering drugs, PCSK9 inhibitors, might not need the results of late outcome studies before approval. However, sponsors of the leading PCSK9 blockers have all initiated such studies, which are necessary in order to gain reimbursement for these new drugs unless outcome studies prove they will reduce heart attacks and strokes beyond that seen with statins. Outcome studies may last three to six years and require 10,000 to 25,000 patients, costing as much as $500 million. Ideally, successful studies will show the real value of new medicines with regards to long-term health benefits.

From "The Growing Need for Outcome Studies and the Impact on R&D Costs"

Forbes (12/02/13) LaMattina, John

Grant Opportunities

Mentored Career Development Award in Biomedical Big Data Science for Clinicians and Doctorally Prepared Scientists (K01)

As part of its Big Data to Knowledge (BD2K) initiative, the National Institutes of Health (NIH) has issued a number of funding opportunity announcements (FOAs), seeking to increase the number of researchers skilled in the science of Big Data and to boost general competencies in data usage and analysis throughout the biomedical research workforce. This BD2K FOA is for a mentored career development award in the area of Big Data Science. The goal is to support additional mentored training of scientists who will gain the knowledge and skills necessary to be independent researchers and also work in a team environment to develop new Big Data technologies, methods, and tools for basic and clinical research. NIH plans to commit $1.5 million to fund six or seven awards in fiscal year 2015. Applications are due on April 1, 2014.

From "Mentored Career Development Award in Biomedical Big Data Science for Clinicians and Doctorally Prepared Scientists (K01)"

Grants.gov (01/17/14)

GSK Forms Oncology Clinical and Translational Consortium

The NANETS (North American Neuroendocrine Tumor Society) Young Investigator Award aims to support young investigators as they pursue basic and/or translational research focused on neuroendocrine tumors. The award will provide $50,000 for one year. Candidates must have an MD, PhD, DO degree or equivalent, and they must be in the first five years of a faculty appointment in an accredited medical school or other institution in North America. Applications are due by June 30, 2014.

From "NANETS Young Investigator Award"

North American Neuroendocrine Tumor Society (12/27/13)

ICA 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 Program include epidemiology/burden of disease (especially 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. 28, 2014.

From "ICA Pilot Research Program"

Interstitial Cystitis Association (12/27/13)

Seeding Collaborations for Translational Research to Discover and Develop New Therapies for Diseases and Conditions within NIDDK's Mission (Revisions)

A new funding opportunity announcement aims to seed collaborations that enable translational research for the discovery and development of therapies for diseases and conditions of interest to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The FOA encourages collaborations through revisions to active NIDDK R01 research project grants, which enables the Program Director/Principal Investigator to propose an expansion of the specific aims to develop collaborations and approaches that facilitate translational research on target identification, early-stage pharmacological validation, and lead optimization and preclinical development. Application budgets are limited to $75,000 direct cost per year, and the total project period for an application submitted may not exceed two years.

From "Seeding Collaborations for Translational Research to Discover and Develop New Therapies for Diseases and Conditions within NIDDK's Mission (Revisions)"

NIGMS (12/12/13)

Instrument Development for Biological Research

The National Science Foundation (NSF) announced the Instrument Development for Biological Research program, which supports the development, production, and distribution of novel instrumentation that addresses demonstrated needs in biological research in areas supported by NSF biology programs. These systems would...
benefit a broad user community through mass distribution of the technology. The program accepts two types of proposals: those for innovation, developing novel instrumentation that provides new research capabilities, and those for bridging, transforming "one of a kind" prototypes or high-end instruments into devices that are broadly available and utilisable without loss of capacity. Applications are due by July 25, 2014.

From "Instrument Development for Biological Research"
National Science Foundation (12/12/13)

Support of Competitive Research (SCORE) Pilot Project Award (SC2)

The National Institutes of Health has announced the Support of Competitive Research (SCORE) Pilot Project Award (SC2). The developmental program is designed to boost the research competitiveness of faculty and research base of institutions with a historical mission and/or demonstrated track record of training and graduating students from backgrounds underrepresented in biomedical research. The SC2 award is intended to help investigators, usually in their earlier stages of development, test a new idea or gather preliminary data for a new line of research. Applicants must be able to spend at least 50 percent of full-time effort on conducting the proposed research. Applications for the next cycle are due by Jan. 25, 2014.

From "Support of Competitive Research (SCORE) Pilot Project Award (SC2)"
NIH Grants (12/06/13)