



ACTS ASSOCIATION FOR CLINICAL AND TRANSLATIONAL SCIENCE

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Translational Science 2015: Joint Opening Plenary Speakers

Join Drs. Robert Califf and Petra Kaufmann to hear their opening remarks at the Translational Science 2015 meeting.



Robert M. Califf, MD
 Director, Duke Translational Medicine Institute,
 Vice Chancellor for Clinical and Translational Research
 Duke University Medical Center



Petra Kaufmann, MD, MSc
 Clinical Innovation Director
 National Center for Advancing Translational Sciences
 (NCATS)

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DEADLINE APPROACHING! Translational Science 2015 Joint Awards Program and Trainee Travel Awards

February 2015

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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

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In the sixth year of the Translational Science meeting, the sponsoring and partnering organizations of ACTS and AFMR will acknowledge the [outstanding contributions](#) of investigators and educators in the field. The recipient of each award will be recognized during Translational Science 2015, April 16-18, 2015 in Washington, DC and be given five minutes to make a presentation.

Also, members are invited to [nominate one trainee](#) for the Burroughs-Wellcome Fund Trainee Travel Award to attend the Translational Science 2015 Meeting. This includes complimentary registration to the meeting and up to \$600 to defray travel costs. Trainees will benefit with special sessions designed for trainees such as "Meetings with Program Officers," poster sessions, and networking opportunities.

All awards nominations are due by **February 13, 2015**.

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Register Now for Translational Science 2015 to Catch the Early Bird Rate!

Early-bird registration ends on February 27, 2015

Take advantage of the early bird discount when registering for the Translational Science 2015 meeting. This year's meeting will encompass a wide variety of opportunities including education, poster sessions, mock study sessions, community engagement, regulatory science sessions and insightful plenary speakers.

Register Now!

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Hotel Registration Deadline Approaching

Translational Science 2015 Annual Meeting will be held at the Omni Shoreham Hotel in Washington, D.C. on April 16th-18th, 2015. A group rate at the hotel will be available for meeting attendees. As a premier travel and conference location, April is a busy time of year in Washington, D.C. To maximize your travel budget, it is best to book your travel and accommodations early! Many rooms have already been booked and space is limited.

If you are a student attending Translational Science 2015 and are interested in obtaining additionally discounted room rates, please contact the staff at info@actscience.org or (202)-367-1119 for more information.

If you would like to make a reservation by phone, please call (202) 234-0700. Group rate for Translational Science Annual Meeting attendees will be available until March 25, 2015.

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From the Hill--ACTS Advocacy News

The President released his fiscal year (FY) 2016 Budget Request to Congress at the

beginning of February. This non-binding proposal lays out the administration's funding priorities and marks the symbolic beginning of the appropriations process. [Check out the funding priorities.](#)

The House Energy & Commerce Committee has released a discussion draft of the 21st Century Cures Initiative. This legislation is focused on streamlining clinical trials and regulatory systems to improve therapy development and health outcomes. Key provisions can be found [here](#).

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Translational Science News

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Translational Science News

FDA Commissioner Hamburg to Step Down After Six Years

Margaret A. Hamburg, commissioner of the Food and Drug Administration (FDA), will step down from her post in March. Dr. Hamburg has led the FDA since 2009. During this time, the agency has accelerated drug approvals by introducing a breakthrough therapy designation for experimental treatments, overhauled how compounding pharmacies are regulated after a deadly meningitis outbreak, and launching initiatives to phase out trans fats in food and require calorie counts on restaurant menus. Dr. Stephen Ostroff, FDA's chief scientist, will serve as acting head of the agency while a new commissioner is found. Dr. Hamburg recently named Duke University's Dr. Robert Califf as the FDA's deputy commissioner for medical products and tobacco.

From "FDA Commissioner Hamburg to Step Down After Six Years"
Bloomberg (02/05/15) Edney, Anna

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Obama Announces \$215 Million Precision-Medicine Genetic Plan

On Jan. 30, President Obama announced a \$215 million plan to gather genetic data on 1 million or more Americans in an effort to identify genetic causes of disease and discover new drugs targeting mutations. Under the plan, the National Institutes of Health (NIH) would receive \$130 million for a genetic mapping project, while the National Cancer Institute would receive \$70 million to study genetic causes of cancer. Additionally, the FDA would get \$10 million to evaluate new diagnostic devices and drugs, while \$5 million would be used to build the computing and privacy components of the genetic-data network. Funding for the initiative requires congressional approval, but bipartisan support has been increasing for expanded research at the NIH. In an interview, NIH Director Francis Collins remarked, "A million [people] would be an enormous advance, particularly if it could be done in a coordinated fashion." Jeffrey Leiden, CEO of Vertex Pharmaceuticals Inc., says the new effort represents "a very important and necessary first step," though he said more needs to be done. After the cystic-fibrosis gene was discovered in 1989, it took Vertex until 2012 to obtain approval for the first drug treating a genetic mutation. An estimated 1,650 patients nationwide who have this mutation are candidates for Vertex's Kalydeco drug.

From "Obama Announces \$215 Million Precision-Medicine Genetic Plan"
Wall Street Journal (01/30/15) Burton, Thomas M.; Rockoff, Jonathan D.; Winslow, Rob

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U.S. Lawmakers Seek to Revamp Biomedical Research

A bipartisan group of U.S. House lawmakers unveiled a draft of their proposal to speed the translation of research into medicine. Dubbed 21st Century Cures, the effort hopes to facilitate research and development at the National Institutes of Health (NIH) and Food and Drug Administration (FDA). The initiative is being led by Reps. Fred Upton (R-Mich.), chair of the Energy and Commerce Committee, and Diana DeGette (D-Colo.). During the past nine months, the lawmakers met with officials from the NIH, the FDA, patient advocacy groups, and pharmaceutical companies to form their plan. "Everything is on the table as we hope to trigger a thoughtful discussion toward a more polished product," Upton said in a statement. The draft bill calls for increasing funding for NIH's National Center for Advancing Translational Sciences (NCATS), in particular for an undertaking to repurpose established drugs for other diseases. The plan also seeks more cash for the NIH's Common Fund, which supports initiatives that are not applicable to any one NIH institute. In addition, the proposal would expand NIH's authority to fund "high-risk high-reward" research, create new programs to support young scientists, and curb the amount of red tape in the NIH's grant process. Another aspect of the plan is granting longer market-exclusivity periods to pharmaceutical and device companies that make therapies for rare diseases and other much-needed products.

From "U.S. Lawmakers Seek to Revamp Biomedical Research"
Nature (01/28/15) Reardon, Sara

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Early Building Blocks of the Learning Health System Falling Into Place

Experts say today's health IT advancements are helping lay the groundwork for a learning health system, where health systems share data to learn about the causes and treatments of disease. Bruce Eckert with consulting firm Beacon Partners says obstacles to overcome include problems with data mismatch, especially patient-matching. It will also be necessary to standardize data exchange and analytics to ensure people are using the same ontologies, code sets, and definitions as well as workflows and data collection. There are 11 clinical data research networks funded by the federal Patient-Centered Outcome Research Institute (PCORI), including the National Pediatric Learning Health System (PEDSNet) and the Chicago Area Patient-Centered Outcomes Research Network (CAPriCorn). PCORI Executive Director Joe Selby said the objective is to harness "the vast data locked within health systems and clinical settings, as well as information and experiences reported by patients themselves. ... Our goal is to use the power of large sets of healthcare data, under policies developed with the help of patients, to enable more rapid and cost-effective clinical research."

From "Early Building Blocks of the Learning Health System Falling Into Place"
Healthcare Informatics (01/22/15) Raths, David

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Grant Opportunities

BRAIN Initiative: New Concepts and Early-Stage Research for Large-Scale Recording and Modulation in the Nervous System (R21)

The National Institutes of Health (NIH) has issued a funding opportunity announcement (FOA) for the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, which seeks to understand how electrical and chemical signals code information in neural circuits and give rise to sensations, thoughts, emotions and actions. While previous BRAIN-related FOAs have focused on developing novel technology or optimizing existing technology ready for in-vivo proof-of-concept testing and collection of preliminary data, the new FOA is looking for new and untested ideas that are in the very earliest stages of development. NIH plans to fund approximately 15 awards, with a total of \$6 million over two years. The combined budget for direct costs for the two-year project period may not exceed \$300,000, and no more than \$200,000 can be requested in any single year. Applications are due by April 16, 2015.

From "BRAIN Initiative: New Concepts and Early-Stage Research for Large-Scale Recording and Modulation in the Nervous System (R21)"
NIH Grants (01/30/15)

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Maximizing Investigators' Research Award (R35)

The National Institute of General Medical Sciences (NIGMS) has announced the Maximizing Investigators' Research Award (MIRA), which is intended to provide support for all of the NIGMS-related research in an investigator's laboratory. The new program is expected to increase the stability of funding for NIGMS-supported investigators; increase flexibility for investigators to follow important new research directions as opportunities arise; more widely distribute funding among the nation's highly talented and promising investigators to increase overall scientific productivity and the chances for important breakthroughs; reduce the time spent by researchers writing and reviewing grant applications, allowing them to spend more time conducting research; and enable principal investigators to devote more time and energy to mentoring junior scientists in a more stable research environment. This funding opportunity announcement will test the feasibility of this grant mechanism via a pilot program with restricted eligibility. NIGMS plans to commit \$60 million in fiscal year 2016 to fund up to 100 awards, with a maximum project length of five years. The application deadline is May 20, 2015.

From "Maximizing Investigators' Research Award (R35)"
NIH Grants (01/27/15)

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Metabolomics Core for the Undiagnosed Diseases Network (UDN) (U01)

The National Institutes of Health's (NIH) Common Fund has announced a funding opportunity to create a Metabolomics Core to support clinical and laboratory findings of the Undiagnosed Diseases Network (UDN). Applications must include a plan to provide comprehensive analytical methods, analyses, technologies, and metabolomics expertise to the UDN to aid in clinical diagnosis and investigate potential mechanisms underlying phenotypic changes in patients, including the need to create specialized, "boutique" assays and methods of measurement in analyses of both normal and abnormal compounds of the diseased metabolome. Total program funding is \$1 million, and the application deadline is April 15, 2015.

From "Metabolomics Core for the Undiagnosed Diseases Network (UDN) (U01)"
NIH Grants (01/21/15)

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