



ACTS ASSOCIATION FOR CLINICAL AND TRANSLATIONAL SCIENCE

Connection

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July ACTS Member Highlight: Tufts University School of Medicine

Point Person Project: Creating a National Patient Recruitment System



Jonathan M. Davis, MD, Professor of Medicine, Tufts University School of Medicine, faced a problem – recruiting patients for pediatric clinical trials was proving to be quite challenging and studies were feeling the effect of low enrollment.

“Studies were having a hard time getting off the ground,” says Davis. “One company worked for two years to enroll patients in a study at multiple sites and recruited only three subjects. We thought, why don’t we try something simple? Let’s identify someone at each site to help,” says Davis.

The Point Person Project was envisioned as a way of addressing the unique challenges associated with recruiting investigators and patients for pediatric clinical trials. The Project began with members of the former CTSA Consortium Child Health Oversight Committee (CC-CHOC) Operations Group and evolved into a national network of navigators to find investigators for research opportunities. “Point People” were identified at CTSA institutions as important contacts for recruitment.

For more, please [click here](#) to see the full story.

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August: ACTS Member Highlight

Coming soon in the August 27th issue of ACTS Connection:

A team of researchers from the Keck School of Medicine of USC, Children’s Hospital Los Angeles (CHLA) and the USC Viterbi School of Engineering have developed a tiny pacemaker for unborn babies with a potentially fatal heart problem. Learn more about this story in the next issue of ACTS Connection!

Share Your Exciting News Stories With Us! Does your institution have news you want to share with the *ACTS Connection* readership? Do you have an investigator doing something innovative? Let us know! From innovative projects, star scholars and trainees, to award winning faculty, help us share the news that is important to you by submitting it through our [online form](#).

Your news may be shared on the ACTS website, and other ACTS social media sources!

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New From the Hill--ACTS Advocacy News House of Representatives Passes 21st Century Cures Act

July 23, 2015

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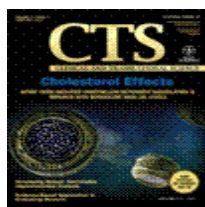
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The House of Representatives recently passed the 21st Century Cures Act (H.R. 6). In order to secure bipartisan support and endorsements from key legislators, the final bill underwent numerous changes from the version that was reported out by the Energy & Commerce Committee previously. Ultimately, the legislation that passed the House is a mixed-bag for the research and patient care community. In H.R. 6, there are numerous industry-friendly provisions designed to incentivize and stimulate treatment development and approval. However, concerns persist that the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) will not receive the funding they need to accommodate new programs and activities, which would further strain annual budgets that are already stretched dangerously thin. Further, patient watchdogs continue to raise concerns that the legislation seeks to relax standards for evidence related to safety and efficacy of new therapies in ways that could jeopardize safety and wellness.

Read more details on H.R. 6 (21st Century Cures Act) by [clicking on the ACTS Advocacy page](#).

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Did you read the June Issue CTS Journal? It's still available!



The latest issue of Clinical and Translational Science are now available with abstracts from Translational Science 2015. To access the most recent edition [click here](#).

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Save the Date Now for Translational Science 2016

Mark Your Calendars! Translational Science 2016 will take place April 13-15 at the Omni Shoreham Hotel in Washington, DC. Registration for Translational 2016 is expected to open in December 2015.

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Translational Science News

More Collaboration, Research Needed to Develop Cures
House Votes to Boost Funding for Medical Research
Precision Medicine Initiative Gears Up

Grant Opportunities

AHRQ Patient-Centered Outcomes Research Clinical Decision Support Learning Network (U18)
International Research Scientist Development Award (IRSDA) (K01)
NASA Translational Research Institute

Translational Science News

More Collaboration, Research Needed to Develop Cures

Despite the Food and Drug Administration's (FDA) rapid drug approval process, drug discovery and development is not keeping pace for some diseases, writes Dr. Robert Califf, FDA's Deputy Commissioner for Medical Products and Tobacco. One key obstacle is a lack of understanding of the biology of disease, and a new FDA [report](#) questions why many diseases are lagging behind while others have a healthy pipeline of new therapies in development. The report notes that for Alzheimer's and many rare diseases, there is still a lack of basic information about what causes these conditions and how they can be treated or slowed. Califf writes, "These are exciting times as we experience simultaneous revolutions in the biological and information sciences." He adds that they will continue to work to speed patient

access to safe and effective therapies and to encourage innovation, but "it will take a collaborative effort to improve our nation's understanding of certain diseases and to translate any resulting scientific discoveries into cures."

From "More Collaboration, Research Needed to Develop Cures"
FDA Voice blog (07/16/15) Califf, Robert

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House Votes to Boost Funding for Medical Research

The U.S. House of Representatives overwhelmingly passed on July 10 a bipartisan bill that would increase federal funding for medical research and accelerate Food and Drug Administration (FDA) approvals for many new drugs and devices. The 21st Century Cures Act, which was passed with a vote of 344 to 77, would require the FDA to consider doctors' clinical experience with a drug, rather than only using randomized clinical trials. In addition, it would encourage more use of factors such as biomarkers, rather than longer-term trials in the assessment of drug and device efficacy. The bill would also raise National Institutes of Health funding by \$8.75 billion over five years, for projects including President Barack Obama's "precision medicine" initiative and another to collect genomic data on more than 1 million U.S. volunteers.

From "House Votes to Boost Funding for Medical Research"
Wall Street Journal (07/10/15) Burton, Thomas M.

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Precision Medicine Initiative Gears Up

Both government and private groups are beginning to advance the goals of the \$215 million Precision Medicine Initiative (PMI) announced earlier this year. Government agencies, health providers, researchers, and patients are making health data more portable, helping patients access and share their health information, protecting patient privacy and choice, and supporting new research platforms that bring together researchers and participants. The White House has unveiled draft guiding principles to increase the privacy of volunteers who share their genetic and health data under PMI. The White House also announced that the Office of the National Coordinator for Health IT and HHS Office for Civil Rights will work together to address barriers to patients who try to access their health information.

From "Precision Medicine Initiative Gears Up"
Health Data Management (07/09/2015) Slabodkin, Greg

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Grant Opportunities

AHRQ Patient-Centered Outcomes Research Clinical Decision Support Learning Network (U18)

The Agency for Healthcare Research and Quality (AHRQ) has issued a funding opportunity announcement calling for applications to create a Patient-Centered Outcomes Research (PCOR) Clinical Decision Support (CDS) Learning Network. This network will engage stakeholders in the dissemination and implementation of PCOR findings through CDS and promote incorporation of PCOR into clinical practice. Engaging stakeholders will help achieve the goal of CDS becoming a shareable, useful public resource. Under a Cooperative Agreement, AHRQ will fund one award of up to \$500,000 in 2016, with total costs for a project awarded not to exceed \$2 million for the entire project period, which may not exceed four years. The application due date is Nov. 13, 2015.

From "AHRQ Patient-Centered Outcomes Research Clinical Decision Support Learning Network (U18)"
NIH Grants (07/09/15)

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International Research Scientist Development Award (IRSDA) (K01)

The National Institutes of Health's (NIH's) Fogarty International Center (FIC) is soliciting applications for the International Research Scientist Development Award. This grant will provide support and protected time (3-5 years) to advanced

postdoctoral U.S. research scientists and junior faculty for an intensive, mentored research career development experience in a low- or middle-income country (LMIC). FIC invites applications from early-career investigators who propose career-development activities and a research project related to health priorities of an LMIC. NIH will contribute up to \$75,000 a year toward the recipient's salary. The deadline for the next application cycle is March 2, 2016.

From "International Research Scientist Development Award (IRSDA) (K01)"
NIH Grants (07/07/15)

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NASA Translational Research Institute

The NASA Human Research Program is establishing a Translational Research Institute to translate promising methodologies into validated prediction, prevention, monitoring, maintenance, and treatment capabilities for human health and performance during exploration missions. The virtual institute also will provide a translational workforce and provide opportunities for scientists to propose new NASA research and apply knowledge and expertise to reducing human exploration risks. The institute is soliciting applications for the award of a Cooperative Agreement for educational, nonprofit, and commercial organizations. The application deadline is Jan. 6, 2016.

From "NASA Translational Research Institute"
NASA News (07/01/15)

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