July 2013 Connection

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New York Times Highlights Adaptive Clinical Trials

In an article entitled "Do Clinical Trials Work?," published on July 13, Clifton Leaf of the New York Times described the challenges in clinical trial design and highlighted personalized medicine approaches. The work of Dr. John Ioannidis, who was a keynote speaker at Translational Science 2012 and a member of CTSAs at Stanford and Tufts, was mentioned. Dr. Ioannidis has shown that the apparent "positive" results of some clinical trials are due to chance in his highly cited 2005 publication (JAMA 294: 218-228, 2005). The New York Times article goes on to describe new adaptive clinical trial designs, being used in the breast cancer study I-SPY 2.

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News from ACTS

UCSF-UC Berkeley Trainees Start A New Translational Science Facebook Group

A group of trainees in the Master in Translational Medicine program jointly sponsored by UC-Berkeley and UCSF have started a translational science Facebook group. Their goal is to publicize recent findings in translational medicine. The group also hopes their efforts will inspire other trainees to create Facebook pages and eventually to link up as a network.

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Washington Update

Congressional leaders have returned from the July 4th recess and are working on several high-profile legislative topics. The Senate-passed comprehensive immigration reform bill is pending in the House of Representatives, where its fate remains uncertain. Meanwhile, the House continues to highlight its dysfunction by stumbling on the bipartisan farm bill, which includes much-needed revisions to agriculture and

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nutrition programs, and stalling on reforms to keep student loan interest rates low.

House and Senate appropriations committees have begun their annual mark-ups of appropriations bills for fiscal year 2014. Progress is uneven on the 12 annual measures. The House has considered and passed several of its funding bills for the military and Veterans' Administration, but has not moved forward on the bill for the Department of Health and Human Services (HHS) and the Department of Education. The Senate Appropriations Committee, which usually waits until the House passes its appropriations bills, instead is moving forward on its own version of the HHS/Education spending plan absent input from the other side of the Capitol.

The Senate Appropriations Committee recently marked up the chamber's FY 2014 Labor-HHS-Education (LHHS) Appropriations bill. In a positive move for federal clinical and translational research and research training programs, the Senate FY 2014 LHHS Appropriations bill increases funding for the National Institutes of Health (NIH) by roughly $1.8 billion dollars. If enacted, this increase would bring FY 2014 funding for NIH up to nearly $31 billion. The Senate's allocation would restore funding lost through sequestration and then add an additional 1% to NIH's budget. It is important to note that the Senate bill also prioritize clinical and translational research programs by recommending increases for the Institutional Development Awards Program, the Cures Acceleration Network, and other activities.

Beyond NIH, additional federal medical research and public health programs fared well under the Senate's FY 2014 LHHS appropriations bill. In order for these funding increase to be secured in any final appropriations measure, the community will need to continue to engage members of Congress, particularly in the House of Representatives, and advocate for adequate funding for clinical and translational research and research training programs.

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Connection Seeks a Volunteer Editor!

Do you like to write? Do you follow the popular and scientific literature on translational science? If so, Connection is looking for a new volunteer editor. This position should take only a few hours each month, but you would be contributing to promoting the field of translational science. This position might be a unique addition to your Curriculum vitae! Send an email to info@actscience.org along with contact information and a description of your current position and interests.

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Make Translational Science 2014 YOUR Meeting!

The Program Committee for Translational Science 2014 is currently working on the program content for the meeting. Dr. Harry Shamoon, co-chair of the Program Committee, has requested suggestions from members on topics, session, and speakers. This unique meeting, to be held in Washington, DC on April 9-11, 2014, offers extraordinary opportunities to network, learn new techniques, and hear the latest findings in translational medicine. Please send your suggestions to info@actscience.org and plan to attend!

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Translational Science News

NCATS Eyes Changes to CTSA as Sequestration Limits Options

The National Institutes of Health (NIH) plans to enhance its Clinical and Translational Science Awards (CTSA) program through more robust leadership, standardized evaluation of centers, greater collaboration and transparency, and strengthened engagement with patient groups. These proposals are based on recommendations made by the Institute of Medicine (IOM) in a report. Christopher P. Austin, director of the National Center for Advancing Translational Sciences (NCATS), is concerned that incorporating these recommendations could be hampered by across-the-board federal budget cuts or "sequestration." Austin says the NIH will convene a working group of NCATS advisory board members and others to advise him on implementing IOM's recommendations quickly. NCATS, which oversees the CTSA program, will intensify involvement in CTSA by establishing goals and a new working group of key stakeholders, says Austin. He also backed an IOM recommendation to create a new "innovations fund." The fund would pay for strategic initiatives within and outside the NIH, including pilot studies and resource-sharing initiatives.

From "NCATS Eyes Changes to CTSA as Sequestration Limits Options"
Genetic Engineering & Biotechnology News (06/25/13)

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Connecticut's $200M Bioscience Fund Makes Translational Research a Priority

Connecticut is making translational research a priority by approving a $200 million bioscience fund in its budget recently. Connecticut Innovations (CI), the state's venture arm, wants to increase commercialization of bioscience research and ideas that will lead to actual products, services, and businesses. "A lot of innovation comes from small companies in universities. That is predicted to drive the future economy. This fund will be a connector to build private, public partnerships," said Claire Leonardi, CEO of CI. Among the fields identified are biomedical engineering, health information management, medical care, medical devices, medical diagnostics, pharmaceuticals, and personalized medicine.

From "Connecticut's $200M Bioscience Fund Makes Translational Research a Priority"
MedCity News (06/26/13) Baum, Stephanie

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'Breakthrough' Designation: Another Powerful Tool in FDA's Toolbox for Expediting the Development and Review of Promising New Drugs ...

The U.S. Food and Drug Administration (FDA) relies on many development and review tools to bring innovative drug products to the public as efficiently as possible, notes Dr. Janet Woodcock, director of FDA's Center for Drug Evaluation and Research. Fast track designation, for instance, is an accelerated approval pathway and priority review designation. Fifty-six percent of novel drugs approved by the Center for Drug Evaluation and Research in 2012 used some combination of these tools to accelerate promising therapies to patients with serious conditions. In July 2012, a provision in the Food and Drug Administration Safety and Innovation Act gave FDA another expedited development tool called the "breakthrough therapy" designation, which

helps expedite the development of new drugs with preliminary clinical evidence indicating that the drug may offer a substantial improvement over existing therapies for patients with serious or life-threatening diseases. The FDA has already received 62 requests to grant this new designation to products under development, and 20 potential innovative new drugs have been granted the breakthrough designation for showing promising early clinical results. To enable industry to better understand each tool and the features of each, the FDA has published a draft guidance titled Expedited Programs for Serious Conditions--Drugs and Biologics. The draft guidance describes the FDA's policies and the threshold criteria for each expedited program. It also defines and discusses key concepts, such as unmet medical need, available therapy, and serious condition, and provides general considerations for products using an expedited program, such as manufacturing and product quality, nonclinical matters, and clinical inspection issues.

From "'Breakthrough' Designation: Another Powerful Tool in FDA's Toolbox for Expediting the Development and Review of Promising New Drugs ..."
FDA Voice blog (06/25/13) Woodcock, Janet

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Restoring Hidden Clinical Data

A group of researchers called Restoring Invisible and Abandoned Trials (RIAT) is taking action to change the fact that just half of all clinical trials are published. Peter Doshi, a postdoctoral scholar in comparative-effective research at Johns Hopkins University, and his colleagues have gathered 178,000 pages of previously private trial data on multiple drugs that came into the public domain as a result of legal battles or the policies of the European Medicines Agency, which started releasing requested trial data in 2010. Doshi and his colleagues have formed a plan of action for those willing to take part in RIAT--they would notify the company who sponsored the research and provide 30 days for the company to commit to a new assessment based on the newly uncovered findings. The company would have a year to provide the information, and if it did not, researchers would contact the BMJ and PLOS Medicine, which have agreed to consider publishing the data. The researchers may also include a critical evaluation of the trial they report in the discussion.

From "Restoring Hidden Clinical Data"
The Scientist (06/18/13) Cossins, Dan

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NIEHS-NCATS-UNC DREAM Toxicogenetics Challenge Opens

A three-month crowdsourced computational competition was launched on June 11 by researchers from Sage Bionetworks, DREAM, the University of North Carolina, the National Institute of Environmental Health Sciences (NIEHS), and the National Center for Advancing Translational Sciences (NCATS). The goal of the NIEHS-NCATS-UNC DREAM Toxicogenetics Challenge is to obtain a greater understanding about how a person's individual genetics can influence cytotoxic response when exposed to broadly used chemicals. To this end, the NIEHS/NCATS/UNC team recently conducted the largest ever population-based in vitro cytotoxicity study by treating 1,086 human lymphoblastoid cell lines representing 9 distinct geographic subpopulations (made available via the 1000 Genomes Project) with 179 pharmaceutical and environmental chemicals. The resulting cytotoxicity data when paired with the publicly available genetic and genomic data on each of the respective cell lines provides a unique dataset that researchers can use to predict toxic responses to chemical compounds across a genetically diverse human population. Sage and DREAM's organizers plan to deploy such tools and incentives throughout the three-month competition period to stimulate a high level of continuous participation. Within a month of opening this Challenge, for example, organizers will go live with a real-time leaderboard for one of the sub-Challenges, which will post the "scores" of submitted predictions as evaluated against a held back portion of the data. Organizers are also encouraging participants to submit code for their models so it can be used by others to build new and improved hybrid models.

From "NIEHS-NCATS-UNC DREAM Toxicogenetics Challenge Opens"
Business Wire (06/11/2013)

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The Right Drug for the Right Patient: Optimizing Clinical Trials Management

In order to deliver the right drug to the right patient, it is essential to conduct the right clinical trial to furnish evidence of safety and efficacy, according to a 2010 report evaluating the U.S. cancer clinical trials system by the Institute of Medicine. One initiative designed to accelerate the drug approval process is the iSpy-2 trial supported by the Foundation for the National Institutes of Health. The goal of iSpy-2 is to pilot an adaptive clinical trial methodology that would allow for the rapid evaluation of new therapeutics and advocate the most promising therapies for accelerated development. But it is also important that reliable testing of multiple drugs within the same protocol be done with equipotent dosing schedules. If not, active drugs might not be successful because of suboptimal administration rather than lack of efficacy. The effective deployment of the iSpy strategy could potentially help accelerate the efficient development of new therapies, providing valuable data to steer future efforts. Meanwhile, the AACI's Clinical Research Initiative, now in its fifth year, provides a forum for clinical research leaders to share information and to promote the national clinical trials enterprise. Special Interest Groups (SIGs) create and implement new tools to share across the AACI cancer center network comprising SIGS for Academic, Industry and Government Relationships; Business and Administration Integration; Managing Networks and Subsites; NCI Clinical Trials Reporting Program; Regulatory and Pre-Activation Processes; Training, Quality Assurance and Monitoring; and Trial Metrics.

From "The Right Drug for the Right Patient: Optimizing Clinical Trials Management"
Association of American Cancer Institutes (06/13) Reid, Tony R.

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Grant Opportunities

AASLD Clinical and Translational Research Awards

The American Association for the Study of Liver Diseases is offering awards of $150,000 over two years in an effort to foster career development for individuals performing clinical and/or translational research in a liver-related area and who have shown commitment to excellence. The Clinical and Translational Research Awards in Liver Diseases aim to make sure that a key portion of young investigator's time is

protected for research, aiming to help young investigators develop independent and productive research careers in liver disease. To be eligible, the project must be clinical or translational, and the candidate must be an advanced fellow or junior faculty member in an accredited North American academic institution. The deadline for application is Dec. 3, 2013.

From "AASLD Clinical and Translational Research Awards"
American Association for the Study of Liver Diseases (06/27/13)

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Beckman Young Investigator Program

The Beckman Young Investigator Program, from the Arnold and Mabel Beckman Foundation, aims to provide research support to promising young faculty members in the early stages of academic careers in the chemical and life sciences, particularly to foster the invention of methods, instruments, and materials that will open up new avenues of research in science. The program is intended to supply funding to individuals with little or no external or internal funding from parent or other organizations. Applicants must have tenure-track appointments in academic and non-profit institutions that conduct fundamental research in the chemical and life sciences, and they must not have completed more than three years in his or her tenure-track or other comparable independent research appointment. Letters of intent are due by Sept. 30, 2013.

From "Beckman Young Investigator Program"
Arnold and Mabel Beckman Foundation (06/27/13)

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National Science Foundation Physics Frontiers Centers

The National Science Foundation's Physics Frontiers Centers program aims to support university-based centers and institutes where the collective efforts of a larger group of individuals can enable transformational advances in promising research areas. The initiative works to promote major breakthroughs at the intellectual frontiers of physics by supplying resources such as combinations of talents, skills, disciplines, and/or specialized infrastructure in an environment where the collective efforts of the larger group can be shown to be seminal to promoting significant progress in the science and the education of students. A successful project will have the potential for a profound advance in physics; creative, substantive activities aimed at enhancing education, diversity, and public outreach; potential for broader impacts; and a synergy or value-added rationale that justifies a center- or institute-like approach. Five to seven awards will be made, with up to $10 million in funding, depending on the availability of funds and the quality of proposals received. Preliminary proposals are due on Aug. 5, 2013.

From "National Science Foundation Physics Frontiers Centers"
National Science Foundation (06/27/13)

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Burroughs Wellcome Fund: Investigators in the Pathogenesis of Infectious Disease

The Burroughs Wellcome Fund is offering five-year awards with $500,000 to support accomplished investigators at the assistant professor level to study pathogenesis, focusing on the interplay between human and microbial biology and looking at how human and microbial systems are affected by their encounters. The funds seek to provide recipients with the freedom and flexibility to pursue new avenues of inquiry and higher-risk research projects that hold potential for significantly advancing the biochemical, pharmacological, immunological, and molecular biological understanding of how microbes and the human body interact. The application deadline is Nov. 1, 2013.

From "Burroughs Wellcome Fund: Investigators in the Pathogenesis of Infectious Disease"
Burroughs Wellcome Fund (06/20/13)

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AGA Research Scholar Awards

The American Gastroenterological Association's Research Scholar Award aims to help young investigators develop independent and productive research careers in digestive diseases by ensuring that a major portion of their time is protected for research. The award is for $180,000 over two years, for young investigators working toward independent careers in gastroenterology, hepatology or related areas. The application deadline is Oct. 18, 2013.

From "AGA Research Scholar Awards"
American Gastroenterological Association (06/20/13)

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Person-Centered Outcomes Research Resource (U2C)

The National Institutes of Health (NIH) issued a Funding Opportunity Announcement to support the creation of a research resource infrastructure for the administration of research investigations using person-centered health outcomes, referred to as the Person-Centered Outcomes Research Resource (PCORR). The primary goal for the PCORR will be to facilitate person-centered outcome research by supporting the use and enhancements of the following measurement information systems: the Patient Reported Outcomes Measurement Information System, the NIH Toolbox for Assessment of Neurological and Behavioral Function, the Quality of Life Outcomes in Neurological Disorders, and the Adult Sickle Cell Quality of Life Measurement Information System. PCORR applicants are expected to have appropriate psychometric, statistical, informatics, and software/hardware expertise and capabilities compatible with the relevant measurement information systems. Previous involvement in PROMIS, NIH Toolbox, Neuro-QOL, and ASCQ-Me may be advantageous but is not required, and this funding opportunity is open to all qualified applicants. The application due date is Sept. 26, 2013.

From "Person-Centered Outcomes Research Resource (U2C)"
National Institutes of Health (06/19/13)

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PCORI Launches 'Engagement Awards' Program to Advance Patient-Centered Outcomes Research

The Patient-Centered Outcomes Research Institute (PCORI) has unveiled a new funding initiative called the PCORI Engagement Awards program. The initiative will offer targeted funding to dozens of groups of patients, clinicians, and other health care community stakeholders interested in supporting the expansion of patient-centered outcomes research (PCOR) and the implementation of PCOR results. Projects will be supported to enhance knowledge of PCOR and its benefits. PCORI will initially invest up to $1.2 million for a training program to build research capacity and fund a series of Pipeline to Proposal Awards. The initial Pipeline to Proposal Awards of up to $15,000 each will help patients and other non-researchers interested in PCOR start forming groups capable of partnering with clinicians, researchers, and others in the health care community. PCORI has issued a Request for Quotes to identify five organizations with the experience and skills to distribute Pipeline to Proposal Award funds and manage these awards. Serving as "Intermediate Funders," each of these organizations will be responsible for helping PCORI select up to 10 patient, stakeholder, or research groups to receive awards of up to $15,000 each. The awards will facilitate the early stages of community-building around a particular topic that can lead to a research question warranting a PCOR project. The Engagement Awards will be distributed in three areas: knowledge, training and development, and implementation.

From "PCORI Launches 'Engagement Awards' Program to Advance Patient-Centered Outcomes Research"
PR Newswire (06/17/13)

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NIAID Resource-Related Research Projects (R24)

The National Institute of Allergy and Infectious Diseases (NIAID) has issued a Funding Opportunity Announcement for investigator-initiated Resource-Related Research Projects (R24) applications. The proposed resource must provide a significant benefit to currently funded, high priority projects in need of further coordination and support in the areas specified. In addition, the proposed resources should be relevant to the scientific areas of the NIAID mission, such as the biology, pathogenesis, and host response to microbes, including HIV; the mechanisms of normal immune function and immune dysfunction resulting in autoimmunity, immunodeficiency, allergy, asthma, and transplant rejection; and translational research to develop vaccines, therapeutics, and diagnostics to prevent and treat infectious, immune-mediated, and allergic diseases. A letter of intent is due by Aug. 11, 2013.

From "NIAID Resource-Related Research Projects (R24)"
NIH Grants (06/07/13)

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