Translational Science 2013 Wrap Up

Thanks to our members for making Translational Science 2013, held in Washington DC on April 17-19, 2013 such a success. This year, nearly 600 attendees gathered to share their research and network with each other to create the ultimate meeting experience.

Attendees listened to keynotes by speakers including Dr. Ezekiel Emanuel and Dr. Christopher Austin, participated in Mock Study Sections, Meetings with Program Officers, Advocacy Training, Hill Visits, along with many more educational and networking opportunities.

Plans for Translational Science 2014 are underway! Let us know what would make this meeting even more valuable to you by sending comments to info@actscience.org.

Visit the ACTS website for additional photographs, program listings and links to presentations from Translational Science 2013.
On Wednesday, April 17, clinical and translational researchers from across the country traveled to Capitol Hill to meet with the offices of their members of Congress as part of the Translational Science 2013 Capitol Hill Advocacy Event. Volunteer advocates were successful in meeting with more than 50 congressional offices representing sixteen states and the District of Columbia.

In recent years, the federal government has made meaningful investments in the full spectrum of medical research activities, with a particular emphasis on initiating and expanding clinical and translational research programs. Furthermore, patient-centered care, comparative effectiveness, and improving healthcare and delivery have become more prominent parts of our federal health system. This emerging focus is related to the fact that legislators have become more aware of the value and importance of clinical and translational research programs, in part due to the personal outreach of volunteer advocates.

For many months, Congress has been debating how to reduce government spending with many proposals including deep reductions in funding for federal programs. In March, automatic government funding cuts known as sequestration went into effect and reduced the resources for many research programs by about 5%. While on Capitol Hill, clinical and translational research advocates educated their elected officials about the harmful impact funding cuts will have on life-improving research activities and the troubling consequences reduced resources can have on the research training and career development pipeline. Ultimately, advocates asked congressional offices to work toward meaningful funding increases for agencies like the National Institutes of Health and the Agency for Healthcare Research and Quality.

The volunteers that advocated during Translational Science 2013 had no special expertise in government or politics. While some training and assistance was provided, these volunteers simply used their stories and experiences to build relationships with the offices of their elected officials. Additional advocacy activities occur on a regular basis throughout the year and all are welcome to participate. As the saying goes on Capitol Hill; the squeaky wheel gets the grease.

**ACTS 2013 Call for Volunteers**

With the completion of the reorganization, ACTS is looking to fill a number of committee positions. Help build your organization!

The following committees are currently soliciting volunteers:

- Advocacy Committee
- Publications, Communications, and Newsletter Committee
- Membership Committee
- Mentoring Committee
- Patient Oriented Research Committee
- Healthcare Implementation, Delivery, and Policy Research Committee
- Translational Science Meeting Committee
- Finance Committee

Visit the ACTS website for complete committee descriptions and to volunteer!

**Translational Science News**

**An Important Step Forward in Addressing the Rare Disease Health Crisis**

Rare diseases are defined in the United States as conditions that affect fewer than 200,000 people at any given time. Roughly 7,000 rare diseases have been identified, and one in 10 Americans is affected by a rare disease. The recently unveiled Rare Disease Impact Report is the first official documentation of the collective impact of rare diseases. The report was commissioned by Shire Human Genetic Therapies in an effort to identify and quantify the health, psycho-social, and economic effect of rare diseases on patients and their families, and comprises more than 1,000 patients, caregivers, physicians, and insurers in the United States and United Kingdom. The report found it takes an average of seven years for a patient with a rare disease in the United States to receive a proper diagnosis, and a patient typically visits up to eight different physicians and receives two to three misdiagnoses. Additionally, 92 percent of physicians in the United States reported that they find it challenging to address the needs of a rare disease patient in a typical office visit, while 98 percent said more office visits are necessary for an initial diagnosis.

From "An Important Step Forward in Addressing the Rare Disease Health Crisis"  
Huffington Post (04/23/13) Boice, Nicole

**Researchers Call for 'Democratization' of Clinical Trials Data**

Three medical researchers from Stanford and Duke universities say there is a need for greater access to data from clinical research. In a recent viewpoint article published online in JAMA Internal Medicine, Robert Califf, Jonathan McCall, and Robert Harrington wrote that both academia and industry must now "catch up to other areas of society" in freeing up of data from clinical research. The authors point out several hurdles to the democratization of information, such as the selective omission of important findings, inaccuracies in published studies, and the use of unreliable data systems. They emphasize key issues that need to be addressed, based on "(1) the value of the research question, (2) the quality of the execution of the research, and (3) the complete and balanced presentation of all relevant data in the publication." However, they also note the availability of robust tools to help overcome these concerns, such as the ClinicalTrials.gov registry and the ongoing movement toward data transparency. If the requirements of ClinicalTrials.gov and other international registries are maintained and strengthened in areas where they are currently insufficient, the benefits will likely be significant.

From "Researchers Call for 'Democratization' of Clinical Trials Data"
FDA Targets 'Disease Areas' for Patient-Centered Research Push

The U.S. Food and Drug Administration (FDA) has chosen several disease areas it plans to address as part of a new initiative on patient-centered research through 2015. The move comes in reaction to a mandate on the newest user fee framework. The FDA has started scheduling several public meetings to obtain feedback on the chosen illnesses from patients and "other interested stakeholders," the agency said in an April 11 Federal Register notice. The fifth version of the Prescription Drug User Fee Act (PDUFA) instructed the FDA to obtain the views of patients regarding diseases that are poorly understood and need better defined clinical trial endpoints for drug development. The FDA has committed to obtaining the public's feedback on 20 disease areas through 2017 via public meetings. The aim is to discuss such things as the impact of the disease on patients' lives and treatment options. Diseases to be evaluated as part of the initiative in fiscal 2013-2015 include breast cancer, HIV, lung cancer, and narcolepsy. Initial disease focus is determined by such things as availability of few or no therapies, chronic diseases, diseases that have a significant impact on subpopulations, and conditions experienced by large numbers of patients.

From "FDA Targets 'Disease Areas' for Patient-Centered Research Push"
Washington Drug Letter (04/15/13) Vol. 45, No. 15

DREAM and Sage Bionetworks Announce Big Data Challenges to Impact Biomedical and Clinical Research

DREAM and Sage Bionetworks will run four Big Data open science Challenges to solve important problems in biomedicine. The "Challenge" concept offers a new way for researchers to rapidly share and evolve predictive models for key questions. The NIHES-NCATS-UNC DREAM Toxicogenetics Challenge will use genetics, genomic and toxicity data to predict individual response to exposure to common environmental and pharmaceutical chemicals. Moreover, the focus will be to predict variation in toxicities across populations exposed to compounds based on the chemical information of the toxic agent and population genetics information. The National Institute for Environmental Health Sciences (NIEHS), the National Center for Advancing Translational Sciences (NCATS), and the University of North Carolina at Chapel Hill (UNC) will provide the data. The other challenges are the Heritage-DREAM Breast Cancer Challenge, the National Brain Tumor Society-DREAM Cancer Prediction Challenge, and the DREAM Whole Cell Parameter Estimation Challenge. Open to anyone for participation, the challenges will launch later this spring.

From "DREAM and Sage Bionetworks Announce Big Data Challenges to Impact Biomedical and Clinical Research"
Business Wire (04/23/2013)

Re-Thinking Clinical Trials for the World of Crowdsourcing

Several innovative ways of accelerating clinical drug development are emerging, such as disruptive business models. Tomasz Sabinski, CEO and founder, of Transparency Life Sciences (TLS), is urging greater transparency in clinical trials to enhance study design, quality, and outcomes while curbing costs. TLS recently obtained Food and Drug Administration clearance of its Investigational New Drug application to examine the use of lisinopril as an adjunct treatment for multiple sclerosis. The company hopes to reduce clinical development costs by 50 percent initially, with an eventual goal of 80 percent savings. TLS uses crowdsourcing, or engaging a community of interest around a therapeutic concept and encouraging open dialogue. Sabinski says it is possible to gain insights and well-informed decisions much faster by curating a discussion among a variety of contributors and perspectives. Meanwhile, a recently created biopharmaceutical consortium of 10 companies called TransCelerate Biopharma hopes to streamline the clinical trial process by tackling longstanding problems. The consortium aims to standardize how clinical data is recorded to minimize human error, enable the use of data across trials, and manage data more efficiently. Another initiative seeks to standardize qualification of trial sites and investigator training in an effort to increase efficiency and quality.

From "Re-Thinking Clinical Trials for the World of Crowdsourcing"
Xconomy (04/16/13) Helloran, Laurie

Collaborations in Translational Research Speed the Drug Pipeline

Translational research can help speed up the drug discovery and development process, enabling products to reach the market faster and more efficiently, as well as significantly cutting costs. Scientists from different areas of expertise collaborate to address problems form multiple angles and through different methods. The Ohio State University Wexner Medical Center comprises 31 academic experts and uses computer science, information science, biomedical informatics (BMI) and information technology tools and methods to support and enable high impact research. "The presence of a formal, academic BMI unit is important to ensure IT and informatics are optimally used to support clinical and translational research," says Philip Payne, chair of the Department of Biomedical Informatics in the College of Medicine. The National Institutes of Health founded the National Center for Advancing Translational Sciences (NCATS) in late 2011, and its impressive achievements include technology that allows a paralyzed individual to use a robotic arm through brainwaves. Academic institutions and biopharmaceutical companies are jointly pursuing translational research on rare diseases as well as neglected diseases. Collaborations also involve small and large companies, such as the translation research into mitochondrial diseases by Edison Pharmaceuticals and Japan-based Dainippon Sumitomo Pharma.

From "Collaborations in Translational Research Speed the Drug Pipeline"
Laboratory Equipment (04/13) Barback, Lily

Grant Opportunities

Geoffrey Been Foundation Alzheimer's Initiative Announces $100,000 Innovation Challenge

The Geoffrey Been Foundation Alzheimer's Initiative has announced the 2013 Geoffrey Been Global NeuroDiscovery Challenge, which seeks to identify male/female
differences in the pathogenesis and presentation Alzheimer’s disease in its various
stages. The goal of the challenge is to develop novel hypotheses that address the
causes and consequences of such differences, including a rationale that is supported
by available data and a detailed research plan that describes how to test the
hypothesis. Hypotheses that can be validated in a secondary phase by mining existing
Alzheimer’s disease databases for analysis of variables associated with biologic
male/female differences in the disease are of particular interest. A written proposal for
this $100,000 award is due by Aug. 31, 2013.

From "Geoffrey Beene Foundation Alzheimer’s Initiative Announces $100,000
Innovation Challenge"
Geoffrey Beene (04/30/13)
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AAMC: Donaghue Grant for Academic Centers

The Research on Care Community at the Association of American Medical Colleges and
the Donaghue Foundation have announced the Donaghue Grant Opportunity for
Academic Centers. The Donaghue Foundation has provided funds to the AAMC to
support these competitive awards designed to improve quality, safety, equity, and
system effectiveness by integrating research into clinical practice. Funding is available
to support two awards, each with a maximum budget of $90,000 per year for three
years (for a total cost of $270,000 each). Proposals are due June 24, 2013.

From "AAMC: Donaghue Grant for Academic Centers"
Association of American Medical Colleges (04/25/13)
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The Developing Evidence to Inform Decisions about Effectiveness (DEcIDE)
Research Network (U19)

The Agency for Healthcare Research and Quality has issued a funding opportunity
announcement seeking Research Program Cooperative Agreement (U19) applications
from organizations that propose a Research Center in outcomes and effectiveness
research and focus on patients served by Medicare or Medicaid and/or Children’s
Health Insurance (CHIP) programs. The announcement is intended to support one to
two comprehensive primary research studies that are designed to produce objective
scientific evidence for informing evidence-based decision-making by Medicare, State
Medicaid, and/or CHIP patients; a dissemination project that transfers knowledge from
a center’s primary research studies to appropriate stakeholders; center infrastructure
including research data, personnel, pilot research studies, learning forums on
research methods, multicenter collaborations, and a stakeholder technical expert panel; and each centers’ shared responsibility in program governance and scientific
oversight through active participation in a multicenter consortia focused on either
Medicare or on State Medicaid/CHIP. The application is due on May 31, 2013.

From "The Developing Evidence to Inform Decisions about Effectiveness (DEcIDE)
Research Network (U19)"
NIH Grants (04/25/13)
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Patient-Centered Outcomes Research Institute to Invest Up to $68 Million to
Develop a National Patient-Centered Clinical Research Network

The Patient-Centered Outcomes Research Institute (PCORI) has issued two funding
announcements for up to $68 million to support development of a National Patient-
Centered Clinical Research Network. The goal is to enhance the nation’s capacity to
efficiently conduct comparative clinical effectiveness research (CER). The two
cooperative agreement funding announcements, announced at a PCORI roundtable
discussion on building a national data infrastructure to advance CER, will support
Clinical Data Research Networks (CDRNs) and Patient-Powered Research Networks
(PPRNs). PCORI will provide up to $56 million to support up to eight new or existing
CDRNs that will develop the capacity to conduct randomized comparative effectiveness
studies using data from clinical practice in large, defined populations. In addition, it
will provide up to $12 million to support up to 18 new or existing PPRNs and their
proponents toward a reusable, scalable, and sustainable research network. PCORI
expects that health systems, clinicians and patients will play key roles in governing
the direction and uses of the networks that this funding will support, and that the
interests of patients will be central to decision-making about the network’s structure,
function, and uses.

From "Patient-Centered Outcomes Research Institute to Invest Up to $68 Million to
Develop a National Patient-Centered Clinical Research Network"
Patient-Centered Outcomes Research Institute (04/23/2013)
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Thrasher Research Fund Early Career Award

The Thrasher Research Fund Early Career Award encourages the development of
medical research in child health by awarding small grants to new researchers. A
variety of research topics important to children’s health are possible, and both
incidence and severity will be considered when determining the significance of a
problem being studied. For the Early Career Award Program, the Fund is especially
interested in applicants who show great potential to impact that field of children’s
health through medical research. There are three funding cycles per year for this
award, and letters of intent for the next deadline are due by June 7, 2013.

From "Thrasher Research Fund Early Career Award"
Thrasher Research Fund (04/18/13)
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Ellison Medical Foundation: New & Senior Scholar Awards in Neuroscience
2013

The Ellison Medical Foundation’s new Neuroscience Scholar Awards program aims to
give researchers the resources they need to develop innovative research programs
that seek to gain insight into the fundamental molecular and cellular mechanisms that
underlie normal biological function and, when dysfunctional, that lead to illness. The
program is intended to support innovative, basic neuroscience research that may fall
outside the scope of traditional funding sources--such as projects involving the
application of new concepts or new technologies whose feasibility is not yet proven;
projects seeking commonalities among social and anti-social behaviors that might yield
new insights into neural mechanisms of aggression and related violent disorders; or

https://actscience.site-ym.com/?May2013Connection
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projects that aim to bring together diverse scientific disciplines in the study of aggression and social behaviors. Candidates in the first three years of an independent research career will be considered eligible for a New Scholar award, while all other applicants are eligible for the Senior Scholar award. Each New Scholar award will be made for up to $100,000 per year, total costs, for a four-year period. Senior Scholar awards will be made for up to $150,000 direct costs per year, plus full indirect costs at the institution’s National Institutes of Health negotiated rate, for up to four years. A letter of intent for the New or Senior Scholar award is due by June 21, 2013.

From "Ellison Medical Foundation: New & Senior Scholar Awards in Neuroscience 2013" Ellison Medical Foundation (04/18/13)

NINDS Stroke Trials Network--National Data Management Center (U01)

The National Institute of Neurological Disorders and Stroke (NINDS) has issued a funding opportunity announcement to invite applications to participate as a National Data Management Center for the NINDS Stroke Trials Network. The primary goal of the network is to maximize efficiencies to develop, promote, and conduct high-quality, multi-site exploratory phase 1/2 and confirmatory phase 3 clinical trials focused on key interventions, as well as biomarker-validation studies that are immediately preparatory to trials, in stroke prevention, treatment, and recovery with the objective to have a balanced portfolio between all three approaches. The network will include multiple regional coordinating stroke centers around the U.S. representing a larger number of community stroke centers all coordinated through separate National Clinical Coordinating and Data Management Centers. Projects will be developed both from investigators within the network as well as from investigators or industry partners outside of the network, so the data center for the stroke network must be able to efficiently collaborate with all parties. A letter of intent is due by July 1, 2013, and the application is due by Aug. 14, 2013.

From "NINDS Stroke Trials Network--National Data Management Center (U01)" NIH Grants (04/18/13)

The Gerber Foundation Pediatric Research Awards

The Gerber Foundation is accepting proposals for research awards for health and/or nutrition-related research having a significant impact on issues facing infants and young children from the first year before birth to age three. The foundation is especially interested in new approaches to solving newborn or pediatric problems or emerging issues with a predictable time frame to clinical application. Projects should be focused on issues faced by care providers that, when implemented, will improve the health, nutrition and/or developmental outcomes for infants and young children. For this cycle, the full proposal is due by August 15, 2013.

From "The Gerber Foundation Pediatric Research Awards" Gerber Foundation (04/18/13)

GSK Plans $1 Million Prize to Jump-Start 'Electroceuticals'

GlaxoSmithKline will offer a $1 million prize to stimulate innovation in the new field of "electroceuticals." During a global forum this December, the drugmaker will bring researchers together to identify a key hurdle in the field, and the group that is able to overcome that hurdle will win the prize money. A new kind of medicine, electroceuticals, involves targeting diseases with electrical impulses, rather than chemicals or biological molecules found in drugs. The work is still in its early stages, and GSK wants to play a coordinating role in bringing researchers together. GSK also plans to fund up to 40 researchers working in external laboratories.

From "GSK Plans $1 Million Prize to Jump-Start 'Electroceuticals'" Reuters (04/10/13) Hirschler, Ben

Nanoscience and Nanotechnology in Biology and Medicine (R01)

The National Institutes of Health has issued a funding opportunity announcement (FOA) seeking applications from institutions or organizations that apply nanoscience and nanotechnology approaches to address problems in biology and medicine. The purpose of the initiative is to provide support for cutting-edge nanoscience and nanotechnology research that can lead to biomedical breakthroughs and new investigations into the diagnosis, treatment, and management of an array of diseases and traumatic injuries. The FOA will also support research projects that develop new and improved nanotechnology and nanoscience-based tools, methods, concepts, and devices that lead to a better understanding of basic biology in addition to conducting translational biomedical studies. Applications are due by June 5, 2013.

From "Nanoscience and Nanotechnology in Biology and Medicine (R01)" NIH Grants (04/04/13)

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