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IOM Releases CTSA Report

The Institution of Medicine (IOM) released their evaluation report of the Clinical and Translational Science Awards (CTSAs) at the National Center for Advancing Translational Science (NCATS) of the National Institutes of Health (NIH) on Tuesday, June 25. The report is available on line at the IOM website.
While generally positive in tone, the report recommends changes or enhancements in these seven areas:

- "Strengthen NCATS leadership of the CTSA Program
- Reconfigure and streamline the CTSA Consortium
- Build on the strengths of individual CTSAs across the spectrum of clinical and translational research
- Formalize and standardize evaluation processes for individual CTSAs and the CTSA Program
- Advance innovation in education and training programs
- Ensure community engagement in all phases of research
- Strengthen clinical and translational research relevant to child health"

(from the IOM summary).

Dr. Christopher Austin, NCATS Director, applauded the IOM report and declared that work on all seven recommendations would be implemented immediately. His comments are available on the NCATS website.

The IOM report will serve as a guide and benchmark for continued successes in the CTSA program.
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News from ACTS

Programming for Translational Science 2014 begins!—Your Input Needed

The planning committee for Translational Science 2014 program is starting work. We

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are still looking additional committee members, especially trainees, young investigators, nurses, and administrators. Additionally, we are using information from a very short survey that is currently open. To volunteer or take the survey, please see the
ACTS website or send an email to info@actscience.org .

The committee, co-chaired by Dr. Harry Shamoon, Albert Einstein College of Medicine, Yeshiva University, and Dr. Keith Colburn, Loma Linda University, will evaluate information from Translational Science 2013, surveys, and guidance from the ACTS Board of Directors, to create an even better annual meeting for all members of the translational science research field. The committee currently includes Drs. Lars Berglund from the University of California-Davis, Marc Drezner from the University of Wisconsin, Daniel Ford from Johns Hopkins University, Michael Lichtenstein from the University of Texas-San Antonio, Emma Meagher from the University of Pennsylvania, Carol Merchant from NCATS, MingMing Ning from Harvard Medical School, Satish Raj from Vanderbilt, Ellen Seely from Harvard Medical School, Lisa Tannock from the University of Kentucky, and Abraham Thomas from Henry Ford Hospital.

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Washington Update

As automatic across the board funding cuts collectively known as "sequestration" begin taking their toll on federal programs, the impact is being felt by Americans across the country. Severe disruptions in air travel led to mass outrage that drew swift corrective action from Congress. The access to care challenges faced by cancer patients as the sequester reduced Medicare reimbursement rates for oncology therapies and altered sites of care have generated similar frustration, but substantive congressional action has yet to materialize.

Within the clinical and translational research community, the National Institutes of Health (NIH) and other federally-supported medical research agencies are trying to absorb a 5% cut to their fiscal year (FY) 2013 budgets. Recently, NIH issued an operating plan that accounts for the reduced budget. Overall, NIH intends to fund current grants and awards at 95% of their approved level for FY 2013. Individual NIH Institutes and Centers are also working to clarify how they will implement the cut. Some have expressed a preference for honoring current grants, while others have stated an interest in supporting more grants at a lower level of funding.

Clinical and translational research advocates continue to engage lawmakers to educate them about the impact of sequestration on the community and the larger biotechnology sector. There is tremendous concern among patient and voluntary health organizations that stifling research, even temporarily, will create a ripple effect with the potential to delay scientific advancement and the development of new therapies and diagnostic tools. A deeper concern is that after years of near level-funding, a significant reduction to medical research funding will further deter young investigators and lead to a loss of critical mass in the career-development pipeline.

One thing is for certain, if the community wants Congress and the Administration to take corrective action, sustained grassroots advocacy and outreach is essential. Only through personal outreach will Congress learn about the erosion of research efforts and the research workforce, and subsequently, take the tough steps necessary to undo sequestration and confront additional threats to adequate funding.

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NCATS Funds First Round of Drug Repurposing Grants

NCATS announced a first round of grants for drug repurposing. This initiative is a partnership between pharmaceutical companies and researchers. Pharmaceutical companies provide drugs that have been developed and studied for a specific disease target but fail to enter the market, and the researchers evaluate their potential use in other diseases. This "re-use" of developed compounds will allow rapid "redeployment" in further clinical trials and potential new therapies. Nine projects were funded for a total of $12.7 million. Additional information is available on the NCATS website.

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IOM Releases Summary from the Clinical Data Sharing Workshop

The Institute of Medicine (IOM) released a summary from their workshop on Clinical Data Sharing. The summary documents concerns about data sharing but emphasized the value for clinical studies and for patients. The summary is available on the IOM website.

The IOM is currently planning an additional study group which will develop a consensus statement on Clinical Data sharing.

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Translational Science News

FDA Rethinking Personalized Drug Trials

The Food and Drug Administration (FDA) will need to overhaul the existing framework for clinical trials in order to bring customized drug therapies to market faster, according to Janet Woodcock, head of the FDA's Center for Drug Evaluation and Research. This will require drugmakers and clinical investigators to work in different ways to select patients for what ultimately will be smaller trials, she said, speaking at a recent luncheon hosted by the Personalized Medicine Coalition. "Ever smaller subsets of patients are being identified, and we're really going to have to put our heads together and figure out how you study these small subsets of diseases," Woodcock said. "What types of trials and development programs do you do? And when does a subset get so small that you're not going to be able to do a randomized trial?" She estimated that an eighth to half of companies' drug pipelines comprised targeted therapies, and that roughly a third of new entities approved by the FDA in 2012 contained some type of genotyped biomarker in its marketing application. Challenges to targeted therapies include difficulty with obtaining insurance coverage, partly due to their price, Woodcock said. Therefore to silence critics, targeted therapies will need to slow or stop chronic diseases rather than only offer short-term positive benefits, she said.

From "FDA Rethinking Personalized Drug Trials"
MedPage Today (05/22/13) Pittman, David

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U.S. FDA Issues Draft Guideline on Expanded Access to IND for Treatment

The Food and Drug Administration (FDA) has unveiled a draft guidance regarding expanded access to investigational drugs for treatment use. This guidance provides information about certain aspects about the FDA's implementation of its regulations on expanded access to investigational new drugs (INDs) for treatment use. In separate draft guidance, the FDA has provided information related to charging for investigational drugs made available under expanded access programs. In the past, the FDA has been criticized for failing to adequately explain the range of IND mechanisms in regulations or guidance, resulting in disparate access for different types of patients. Access was primarily limited to patients with certain diseases like cancer and HIV infection. To address these concerns, the agency revised its expanded access regulations in 2009 to increase awareness and knowledge about expanded access programs and the procedures for obtaining IND for treatment. The FDA hopes that increasing awareness about expanded access and the procedures to obtain IND could be accessible under three sections--for emergency use, intermediate-size patient populations, and large patient populations under a treatment IND or treatment protocol.

From "U.S. FDA Issues Draft Guideline on Expanded Access to IND for Treatment"
PharmaBiz.com (05/20/13) Vijay, Nandita

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Interview: Chris Austin on How NCATS Wants to Change Drug Development as We Know It

In an interview, Chris Austin, director of the National Center for Advancing Translational Sciences (NCATS), discusses drug development, regulatory science, crowdsourcing development, and translational science. Austin says the three main reasons for why drugs fail are lack of efficacy, toxicity, and business reasons. In both the preclinical space and clinical space, the problems are scientific half of the time, while the other half comprises collaboration, incentive, intellectual property, and credit problems. The current research system, at least in the public sector, is designed to do fundamental research instead of translational results, Austin believes. He notes that the NCATS relies on three Ds: develop, demonstrate, and disseminate. Develop refers to new tools and technologies such as new chemical libraries that address novel parts of chemical space, while demonstrate refers to individual use cases (target, disease, intervention, and so on) to show that a novel approach is effective, and dissemination refers to tools to discuss the cases in a purposeful way with the rest of the community. He says his agency works with industry via general, pre-competitive data/research tools, such as collaboration between NCATS and Eli Lilly, or through direct collaborations, usually with small companies to de-risk individual, unprecedented targets, untreated diseases, or rare diseases. In the future, Austin says he hopes "that within 10 years we will have affected the entire ecosystem, much shorter than that what we're focusing on is being able to pick out individual use cases in each of these domains that we just mentioned to say, 'Here's a better way of doing this. Here's a pilot program.' And we hope that in so doing, others will see that there is a better way of doing this, and pick it up on their own."

From "Interview: Chris Austin on How NCATS Wants to Change Drug Development as We Know It"
Regulatory Focus (05/08/2013) Gaffney, Alexander

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Our Big Idea for Big Data: A National Patient-Centered Clinical Research Network

U.S. healthcare research as conducted today is unsustainable due to tightening research budgets, the accelerating cost of clinical trials, and an influx of insights stemming from new data, writes Dr. Joe Selby, executive director of the Patient-Centered Outcomes Research Institute (PCORI). To ensure that research serves patients more effectively, a new model is needed that fully involves healthcare systems, clinicians, and patients in the process of developing and overseeing the data needed to strengthen personalized medical decision-making. The development of a National Patient-Centered Clinical Research Network is being supported by $68 million in initial funding from PCORI. The aim, writes, Selby, is to provide a nationwide data infrastructure that furthers patient-centered comparative effectiveness research. The proposed network will involve researchers, health systems, clinicians, patients, and other stakeholders from the outset to leverage the vast volumes of healthcare data and convert it into meaningful discoveries. Funding will go towards creating a series of patient networks and health systems networks that will form the overall national network. Up to $12 million will go toward funding the creation of 12-18 patient powered research networks (PPRN), each of which will feature motivated patients that focus on a specific disease or condition. Up to $56 million will be provided to create up to eight clinical data research networks (CDRN) that each will include multiple health systems with the capacity to connect and share large amounts of de-identified electronic health records (EHR) data. Once formed, the PPRNs and CDRNs will cooperate to create, refine, and test models for data-driven patient-centered research projects.

From "Our Big Idea for Big Data: A National Patient-Centered Clinical Research Network"
Patient-Centered Outcomes Research Institute (05/01/2013) Selby, Joe

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Grant Opportunities

Robert Wood Johnson Foundation Health & Society Scholars Program

The Robert Wood Johnson Foundation Health & Society Scholars program offers two years of support to postdoctoral scholars at all stages of their careers to boost the nation's capacity for research and leadership to address the multiple determinants of population health and contribute to policy change. The program, which holds that progress in the field of population health relies on collaboration and exchange across disciplines and sectors, aims to improve health by training scholars to investigate the connections among biological, genetic, behavioral, environmental, economic, and social determinants of health; and develop, evaluate and disseminate knowledge, interventions, and policies that integrate and act on these determinants to improve health. The program will select as many as 12 scholars for two-year appointments starting in the fall of 2014. Scholars will receive an annual stipend of $80,000. The application and reference deadline is Sept. 20, 2013.

From "Robert Wood Johnson Foundation Health & Society Scholars Program"
Robert Wood Johnson Foundation (05/16/13)

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American College of Cardiology Foundation Opportunities

The American College of Cardiology Foundation has announced several research and career development awards. The Young Investigator Awards competition encourages young scientific investigators with progress in the field of cardiology. Awards will be made in the following categories: ACCF/Herman K. Gold Young Investigator Awards in Molecular and Cellular Cardiology; Physiology, Pharmacology and Pathology; Clinical Investigations, Congenital Heart Disease, and Cardiac Surgery; and Cardiovascular Health Outcomes and Population Genetics. The deadline for this award is Oct. 11, 2013. The ACCF/William F. Keating, Esq. Endowment Career Development Award aims to recognize and provide financial support for research efforts by outstanding cardiovascular scholars. The award is to encourage junior faculty in the early phases of their careers in the field of cardiology. Meanwhile, the ACCF/Merck Research Fellowships in Cardiovascular Disease and Cardiometabolic Disorders offers four one-year fellowships to support research in adult cardiology, and the ISCTR-ACCF Cardiovascular Translational Research Scholarship provides financial support for research efforts by outstanding cardiovascular scholars. This scholarship aims to encourage junior faculty in the early phases of their careers in the field of cardiology. The deadline for these three awards is Sept. 23, 2013.

From "American College of Cardiology Foundation Opportunities"
American College of Cardiology (05/16/13)

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NIDCD Research Career Enhancement Award for Established Investigators (K18)

The National Institute on Deafness and Other Communication Disorders (NIDCD) has announced the Research Career Enhancement Award for Established Investigators program. The program seeks to enable established, proven investigators to augment or redirect their research programs through the acquisition of new research skills to answer questions relevant to the hearing, balance, smell, taste, voice, speech, and language sciences. NIDCD expects to fund three to five awards, corresponding to a projected total of $600,000 per year.

From "NIDCD Research Career Enhancement Award for Established Investigators (K18)"
NIH Grants (05/16/13)

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The W.M. Keck Foundation Grant Programs

The W.M. Keck Foundation is offering funding for its Science and Engineering Program and its Medical Research Program. The foundation is looking for breakthrough basic research that is innovative, distinctive, and interdisciplinary; demonstrates a high level of risk; and projects that create new technology, instrumentation, and methodology. For the science and engineering program, the foundation will support institutions pursuing projects that are distinctive and novel in their approach, question the prevailing paradigm, or have the potential to break open new territory in their field. For the medical research program, the foundation wants to support institutions engaged in basic research that is high-risk and has the potential to transform its field. The deadline for both of these awards is Nov. 1, 2013.

From "The W.M. Keck Foundation Grant Programs"
W.M. Keck Foundation (05/16/13)

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Collaborating Centers of Excellence in Regulatory Science and Innovation (U01)

The U.S. Food and Drug Administration (FDA) has issued a Funding Opportunity Announcement to provide support for one or more Collaborating Centers of Excellence in Regulatory Science and Innovation (CERSI). The CERSIs will be established to foster an innovative and thematically coherent approach to advance the field of regulatory science and the Critical Path Initiative toward more effective and efficient product development and evaluation. The FDA/Office of Chief Scientist plan to fund one to two awards, corresponding to a total of $1.4 million, contingent upon the availability of funds. Applications are due by July 8, 2013.

From "Collaborating Centers of Excellence in Regulatory Science and Innovation (U01)"
NIH Grants (05/15/13)

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PCORI Opens Second Year of Research Funding With $81 Million in New Round of Announcements

The Patient-Centered Outcomes Research Institute (PCORI) has opened its second year of funding of patient-centered comparative clinical effectiveness research (CER). PCORI intends to award up to $81 million in this newly announced round of PCORI Funding Announcements (PFAs) and commit to at least $355 million in support for patient-centered CER in 2013. The revised PFAs take into account feedback that PCORI received during previous funding cycles and include several improvements designed to make it easier for applicants to understand the criteria. Applicants must show they have considered how their results could be disseminated and implemented and that they will make their study protocols available so that other interested researchers can seek to replicate their results. The PFAs seek proposals for innovative projects that address the five focal areas of PCORI's National Priorities for Research and Research Agenda: Assessment of Prevention, Diagnosis, and Treatment Options, Improving Healthcare Systems, Communication and Dissemination, Addressing Disparities, and Accelerating Patient-Centered Outcomes Research and Methodological Research. Applications are due Aug. 15, 2013.

From "PCORI Opens Second Year of Research Funding With $81 Million in New Round of Announcements"
Patient-Centered Outcomes Research Institute (05/15/2013)

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Helen Hay Whitney Foundation Postdoctoral Research Training

The Helen Hay Whitney Foundation, which supports early postdoctoral research training in all basic biomedical sciences, is offering grants to help further the careers

of young men and women engaged in biological or medical research. The foundation will accept applications from candidates who have no more than one year of postdoctoral research experience and who have received a Ph.D. degree no more than two years before the deadline, or an M.D. degree no more than three years before the deadline. Applications are due on July 1, 2013.

From "Helen Hay Whitney Foundation Postdoctoral Research Training"
Helen Hay Whitney Foundation (05/09/13)

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