ACTS Leadership Profile: Barry Coller, MD, Board of Directors

I currently serve as Physician-in-Chief and Head of the Laboratory of Blood and Vascular Biology at Rockefeller University and previously I served as Chair of the Department of Medicine at Mount Sinai School of Medicine. My research has focused on platelet physiology and vascular disease, with a focus on antiplatelet therapy. I had the pleasure and excitement of helping to found the Society for Clinical and Translational Science (SCCTS) and serving as the first SCCTS president. I was delighted that SCCTS, ACRT, and APOR decided to merge and even more delighted to be asked to serve on the new ACTS Board. I am the Chair of the ACTS Nominating Committee and our committee has had the responsibility of developing the policies and procedures for conducting the elections specified in the ACTS bylaws. We have been most fortunate in having so many outstanding people volunteering to serve as ACTS committee members, Board members, and officers. ACTS really has great leadership.

My own experiences in translational research include working with the scientists at Centocor to develop the antiplatelet drug abciximab from a monoclonal antibody developed in my laboratory and working with the scientists at Accumetrics to develop antiplatelet therapy monitoring assays (VerifyNow) from an assay developed in my lab. I am currently working on developing a new antiplatelet agent for pre-hospital therapy of myocardial infarction.

The Translational Science meeting provides me with a great opportunity to learn about new programs and policies being developed by NIH and other federal agencies, including the FDA and AHRQ, and exciting new scientific developments in translational research. The highlight for me is the poster sessions where trainees present their research. I find them not only informative, but truly inspirational, knowing that there is a terrific new generation of translational investigators. I also greatly value the opportunity to meet old friends and make new friends, and help build a cultural identity for translational research trainees and their mentors.

News from ACTS

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Washington Update
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FASEB 2015 Excellence in Science Award

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News from ACTS

Translational Science 2014: Early Registration Rates End Soon!

Early registration rates for Translational Science 2014 end on Friday, February 28! Translational Science 2014 is jointly sponsored by the Association for Clinical and Translational Science (ACTS) and American Federation for Medical Research (AFMR). Additionally, we are thrilled to have Biostatistics, Epidemiology, Research Design (BERD), Clinical Research Forum (CR Forum) and our pre doctoral scholars participating this year in the annual meeting. The mission of the meeting is to bring together all of the disciplines involved in clinical and translational research, for the shared benefits of networking and education. Click here to register now.

Meet Our Featured Speakers

Dr. Christopher Austin
Director, National Center for Advancing Translational Sciences, National Institutes of Health

Dr. Bruce Gellin
Deputy Assistant Secretary for Health and Director of the National Vaccine Program Office

Dr. Vicki Seyfert-Margolis
CEO & Founder of MyOwnMed

Dr. Lisa Guay-Woodford
Director, Center for Translational Science Director, CTSI-CN Children's National Health System

For more information and program details, visit www.translationalsciencemeeting.org.

Washington Update

Earlier this month, both the House and Senate quickly passed a measure to raise the debt ceiling, increasing the amount of money that the government is allowed to borrow in order to fulfill its credit obligations. While such an event may seem like routine congressional business, in recent years efforts to raise the debt ceiling have been the focal point of strong partisanship and complicated politics. There is a sense of optimism within the advocacy community that the debt ceiling increase is another strong indication that regular order and bipartisanship have returned to Capitol Hill.

At the beginning of this year, after coming to an agreement on a federal budget, Congress passed a fiscal year (FY) 2014 omnibus appropriations package to fund all federal programs, including clinical and translational research activities. In another positive sign for the advocacy community, the omnibus appropriations package provided meaningful funding increase for many key programs, such as Clinical and Translational Science Awards (CTSA), Institutional Development Awards (IdEA), and Research Centers at Minority Institutions (RCMI). In addition to the new funding, the omnibus package mitigated sequestration cuts, which allows key programs to enjoy even greater budget authority and fund more critical research projects.

Perhaps most importantly, through recent action Congress has already set the federal spending limits for FY 2015, thus avoiding a potentially drawn out and contentious debate over the budget. Appropriators are just beginning their work to decide the FY 2015 funding levels for CTSA, IdEA, RCMI, and other clinical and translational research and research training activities. To ensure that these programs and the full spectrum of medical research receive significant funding increases in FY 2015, members of
Become an Advocate - Participate in Translational Science 2014 Hill Day!

Each year, grassroots advocates from across the country gather in Washington, DC for our annual Advocacy Day. At this event, advocates receive advocacy training and briefings on issues impacting the community before traveling to Capitol Hill to meet with the offices of Members of Congress representing their home state.

This year’s Advocacy Day will be held in conjunction with Translational Science 2014 on April 9. Advocacy Training will be held at the Omni Shoreham Hotel at 8:30 - 10:00 am, followed by Hill Visits at 11:00 am - 3:00 pm. To participate in the advocacy efforts, register for Translational Science 2014.

Translational Science News

J&J Opens Data Vault to Yale in ‘Unprecedented’ Transparency Move

Johnson & Johnson (J&J) has finalized an agreement with the Yale School of Medicine’s Open Data Access Project to provide access to all of its company-sponsored studies. The responsibility of evaluating the scientific merit of data requests will be handled by independent, third-party experts at Yale. J&J has also said it will honor scientific data requests going as far back in time as its data is available, and it will provide detailed clinical study reports and patient-level data rather than just summaries. Yale's Harlan Krumholz, who helped fashion the deal with J&J, stated that, “Many of these trials were never published. But now they’re willing to engage in a crowdsourcing of science. They are allowing people to generate new insights.” However, he said access to the data will require users to have a valid scientific request rather than for commercial or litigious purposes. Joanne Waldstreicher, J&J's chief medical officer, said that in the case of rare diseases, it could be challenging to make patient-level data truly anonymous because so few patients participate in such studies.

From “J&J Opens Data Vault to Yale in ‘Unprecedented’ Transparency Move” Xconomy (01/30/14) Timmerman, Luke

$7 Million Multi-Institutional Contract Creates New York City Clinical Data Research Network

Seven health systems in New York City will be able to share data and recruit patients for clinical trials more effectively under a $7 million contract awarded by the Patient-Centered Outcomes Research Institute (PCORI). The award will create a Clinical Data Research Network (CDRN) in New York City, one of 29 similar health data networks nationwide. These networks will collectively form a new resource known as PCORnet, the National Patient-Centered Clinical Research Network. New York City’s Clinical Data Research Network (NYC-CDRN) will consist of 32 regional organizations that will mutually leverage capabilities and develop systems to support data-networking efforts and advance patient-centered research. The network will initially identify individuals with diabetes, obesity, and cystic fibrosis and will form disease-specific community workgroups. The NYC-CDRN will link medical records for 6 million residents in the city, all records will be anonymized to safeguard patient privacy. Institutions involved in the new project include the four principal medical center participants (Montefiore Medical Center, Mount Sinai Health System, New York-Presbyterian Hospital, and NYU Langone Medical Center); five organizations for patient engagement (Center for Medical Consumers, Consumer Reports, American Diabetes Association, New York Academy of Medicine’s DASH initiative for obesity, and the Cystic Fibrosis Foundation); one practice-based research network of Federally Qualified Health Centers (Clinical Directors Network); one genome center (New York Genome Center); one research-support organization (Biomedical Research Alliance of New York); and the new Cornell Tech Campus.

From "$7 Million Multi-Institutional Contract Creates New York City Clinical Data Research Network" Newswire (01/28/14)

IOM Wants Ideas on Wider Sharing of Clinical Trials Data

The Institute of Medicine (IOM) is seeking public comment on how to share clinical trials data. A “discussion framework” released by the IOM features preliminary guiding principles, defines selected data and data sharing activities, and poses specific questions for researchers, clinical trial sponsors, patients, advocacy groups, and the public. "Clinical trials of medical interventions such as drugs, medical devices, procedures and behavioral interventions generate vast amounts of data, which might be shared confidentially with government regulatory agencies or other parties but are not routinely available to other researchers or the public," IOM said in a statement. "Sharing these data more broadly—while respecting research participants and their privacy—could facilitate new analyses, provide a deeper understanding of therapies, and ultimately provide a sounder basis for clinical care."

From "IOM Wants Ideas on Wider Sharing of Clinical Trials Data" Health Data Management (01/22/2014) Goedert, Joseph

Should Research Subjects Have Access to Their Raw Data?

Researchers at Harvard Medical School and King’s College London assert that research participants should have basic access to the raw data they provide. The act of providing a blood or saliva sample to a biobank should resemble making a monetary deposit in a physical bank, they wrote in an essay in the journal Science. However, information in studies typically flows in a single direction, from research participant to scientists. "From a moral point of view, an ethical point of view, this is a very unequal
relationship," says Harvard Medical School's Jeantine Lunshof, who is involved in the Personal Genome Project that provides open access to participants' genetic data. Lunshof and her co-authors believe such raw data could potentially be brought to a service by participants to help them interpret it. Moreover, if research participants had access to their own data, the transparency could serve as a deterrent to fraud, Lunshof believes. Still, she acknowledges that furnishing raw data to participants would be controversial and challenging in a technical sense, with each field needing to establish standards and define what is raw data and what is a result.

From "Should Research Subjects Have Access to Their Raw Data?"  
Boston Globe (01/23/14) Johnson, Carolyn Y.
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Appistry to Build Out, Support NIH Rare Disease Exome Pipeline

The National Institutes of Health’s (NIH’s) Undiagnosed Diseases Program (UDP) has partnered with Appistry to release a diploid aligner genetic-analysis pipeline developed by the NIH for rare disease diagnosis. The pipeline reference genome to indicate the parental heritage of a patient with a rare disease. "The system creates a diploid genome that takes into consideration the haploblocks of each of the parents, and in that fashion those roughly hundred base pair reads are aligned better and have fewer false positives and fewer false negatives. It gives us a more accurate set of punitive variants to look at," explains William A. Gahl, director of the NIH UDP and clinical director of the National Human Genome Research Institute. He says the pipeline includes GATK, a Broad tool that is also commercialized and supported by Appistry, in addition to other open source and commercial components. The UDP started using the entire pipeline in January, although refinements are still being made. After Appistry began working to streamline some of the pipeline integration, "NIH has been able to make rapid changes and really begin tweaking things to do what they need it to do," says Appistry’s Deborah Ausman. "We are currently speaking with other UDP partners, however, about implementing the pipeline at their sites."

From "Appistry to Build Out, Support NIH Rare Disease Exome Pipeline"  
Bio-IT World (01/22/14) Proffitt, Allisson
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Organovo Announces Collaboration with NIH

The National Center for Advancing Translational Sciences (NCATS) and the National Eye Institute will work with Organovo to improve the way treatments are brought to patients. The two institutes from the National Institutes will use Organovo's NovoGen MMX Bioprinter to develop better and more clinically predictive tissue models. The use of animal models and traditional cell culture models often hampers researchers who are developing new therapies for patients, says Keith Murphy, chief executive officer of Organovo. "We hope to create tissue models that give researchers a much more accurate view of how drugs will behave in human beings before those drugs ever enter clinical trials," he adds. NCATS is looking forward to collaborating on the development of a printable eye tissue and additional tissue models, says Christopher Austin, director of the center. "Developing collaborations like this are central to NCATS' mission," Austin says.

From "Organovo Announces Collaboration with NIH"  
Drug Discovery & Development (01/14/14)
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New Study Aiming to Push Genomics Forward

Regeneron Pharmaceuticals is launching a genomics initiative with Geisinger Health System, which treats 3 million people in Pennsylvania. Regeneron will sequence DNA from approximately 100,000 volunteers among Geisinger’s patients to identify genetic variants related to various diseases, with an aim of gaining insights into developing potential new drugs. Geisinger intends to use the genetic data to improve patient care. "As far as I'm aware, it's the largest clinical sequencing undertaking in this country so far by a long shot," says Leslie G. Biesecker, chief of the genetic disease research branch at the National Human Genome Research Institute, who is familiar with the project. David G. Yancopoulos, the chief scientific officer of Regeneron, said the declining cost of DNA sequencing and his own company’s scientific capabilities will help make the initiative successful. Regeneron will initially sequence only the exome, which comprises just 1 percent to 2 percent of DNA. Geisinger already has extensive electronic medical records on its patients and gathered 45,000 DNA samples. To ensure patient privacy, the medical information and DNA samples given to Regeneron will be anonymized, but Geisinger will know who the patients are and can use that information in their care. For example, if the sequencing indicates that a patient has a mutation linked to a high risk of getting breast cancer, the person might be informed and could take steps to prevent the disease, said David H. Ledbetter, a geneticist and chief scientific officer at Geisinger.

From "New Study Aiming to Push Genomics Forward"  
New York Times (01/13/14) P. B3 Pollack, Andrew
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New Biomarker Development Alliance Aims to Address ‘Urgent’ Need for Standards

The Research Collaboratory at Arizona State University has launched the National Biomarker Development Alliance (NBDA) to address the challenges of creating standards to support end-to-end, evidence based biomarker development. The U.S. Food and Drug Administration approves only 1.5 protein biomarkers each year, and only 100 are used routinely in clinical care. The nonprofit organization will create best practices, guidelines and standard operating procedures for new models of biomarker development, and it will make its data, processes and standards available to the public. The NBDA will organize a consensus conference to define standards for the field that can be agreed to by stakeholder groups. In addition, the alliance will build resources such as a national biomarker repository, a network to reproduce selected biomarker results and a common biomarker database. "Creating the standards and systems for successful biomarker development is complex but achievable through a new generation of networks of stakeholders that integrate knowledge to solve critical problems of this scale," said NBDA co-founder and President Anna Barker.

From "New Biomarker Development Alliance Aims to Address ‘Urgent’ Need for Standards"  
GenomeWeb News (01/13/14)
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Bayer HealthCare Ties Up with Chinese University
A collaboration agreement has been signed between Bayer HealthCare and Peking University that covers a three-year partnership to promote translational research for drug discovery. The collaboration seeks to apply basic research in the therapeutic areas of cardiology, oncology, hematology, and gynecology. Researchers at Bayer HealthCare and Peking University will collaborate on the discovery of new medicines and will set up a joint research hub at Peking University. Andreas Busch, a member of the Bayer HealthCare executive committee and head of global drug discovery, says: “The establishment of this research collaboration with Peking University demonstrates Bayer’s ongoing commitment to China as an important location in our innovation strategy.”

From "Bayer HealthCare Ties Up with Chinese University"
Insider Media (01/09/14)

Grant Opportunities

PCORI Issues Funding Announcements Offering Up to $206 Million in Research Support

The Patient-Centered Outcomes Research Institute (PCORI) is offering up to $206 million to support comparative effectiveness research (CER) designed to answer the health and healthcare questions of greatest concern to patients and other healthcare stakeholders. PCORI is accepting proposals for patient-centered outcomes studies through eight PCORI Funding Announcements (PFAs). These include PCORI’s first call for proposals through its Large Pragmatic Clinical Studies Initiative, awarding up to $90 million to fund up to nine large, multi-year CER studies; up to $20 million to fund up to two trials comparing obesity treatment options in primary care settings; up to $15 million to fund a comprehensive study to determine which clusters of transitional care services work best at reducing preventable hospital readmissions and improving outcomes among at-risk patients; and up to $81 million for the Spring 2014 Cycle of funding under its five broad National Priorities for Research. The deadline for required Letters of Intent for each of these PFAs is 5 p.m. (ET) Friday, March 7.

From "PCORI Issues Funding Announcements Offering Up to $206 Million in Research Support"
Patient-Centered Outcomes Research Institute (02/05/14)

NSF Faculty Early Career Development (CAREER) Program

The National Science Foundation’s Faculty Early Career Development (CAREER) Program offers awards in support of junior faculty who exemplify the role of teacher-scholars through outstanding research, excellent education, and the integration of education and research within the context of the mission of their organizations. A total of 600 standard or continuing grant awards are expected to be made each year, with $220 million per year for new and continuing CAREER awards. Applications are due between June 21-23, 2014, depending on the field of concentration.

From "NSF Faculty Early Career Development (CAREER) Program"
National Science Foundation (02/23/14)

International Collaborations in Infectious Diseases Research (U01)

The National Institute of Allergy and Infectious Diseases is requesting applications from U.S. institutions and collaborating foreign institutions to study infectious diseases (excluding HIV/AIDS) of public health significance in resource-constrained countries. The collaboration must include at least one U.S. institution and one eligible foreign institution, which are defined as low-income economies, lower-middle-income economies, and upper-middle-income economies, as defined by the World Bank. This research aims to increase scientific knowledge on public health-related issues, increase relevant research experience for U.S. and foreign investigators, further the development of research capacity, and promote future collaborative relationships. Applications are due by March 7, 2014.

From "International Collaborations in Infectious Diseases Research (U01)"
NIH Grants (01/23/14)

HHMI Investigator Program Launches National Competition

The Howard Hughes Medical Institute (HHMI) is accepting applications for up to 25 new biomedical research positions, worth about $1.5 million over five years. The national competition is open to basic researchers and physician scientists at more than 200 eligible institutions who study significant biological problems in all of the biomedical disciplines. Individuals selected in the competition will receive a five-year position at HHMI, which is renewable pending favorable scientific review. Applications are due by June 3, 2014, and finalists will be chosen in 2015.

From "HHMI Investigator Program Launches National Competition"
Howard Hughes Medical Institute News (01/15/14)

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. The Fund will consider a variety of research topics that are key to children’s health; both incidence and severity are considered when determining the significance of a problem being studied. For this award, the Fund is especially interested in applicants who show great potential to impact that field of children’s health through medical research. For 2014, the Fund will give up to 30 awards in two funding cycles. The concept submission deadline for the first cycle is March 7, 2014, while the deadline for the second cycle is Sept. 12, 2014.

From "Thrasher Research Fund: Early Career Award"
Thrasher Research Fund (01/09/14)

FASEB 2015 Excellence in Science Award

The Federation of American Societies for Experimental Biology (FASEB) is seeking nominations for its 2015 Excellence in Science Award, which recognizes the significant
accomplishments of female scientists. Nominees should be outstanding women who have made an impact on international science and contributed substantially to training the next generation of scientists. The award recipient will be present an Excellence in Science Award Lecture in 2015 at the annual meeting of a FASEB Member Society. The recipient may choose the topic of her lecture and the meeting at which she will present the lecture. The award includes a $10,000 unrestricted research grant as well as meeting-related expenses. Nominations are due by March 1, 2014.

From "FASEB 2015 Excellence in Science Award"
Federation of American Societies for Experimental Biology (01/09/14)
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