ACTS Leadership Profile: Frederick P. Ognibene, MD, MCCM, FACP

Frederick P. Ognibene is the NIH Clinical Center’s Deputy Director for Educational Affairs and Strategic Partnerships—responsible for programs focused on clinical training and education and the development of NIH intramural/extramural research collaborations. He received a Bachelor of Arts degree in Biology magna cum laude from the University of Rochester, and a MD degree from Cornell University Medical College. He was a resident in internal medicine at the New York Hospital/Cornell Medical Center; a fellow in critical care medicine in the Critical Care Medicine Department, NIH Clinical Center; and has been a NIH tenured senior investigator since 1987. He is a member of the Society of Critical Care Medicine and served as president in 2007. Honors and awards include Alpha Omega Alpha; Master, American College of Critical Care Medicine; Fellow, American College of Physicians; elected to Association of American Physicians 2010; and multiple NIH Director’s Awards.

Currently he is a full time physician-administrator at the NIH Clinical Center and is involved in pedagogical research based on his leadership role in clinical research training and medical education. However, prior to this current administrative role he was a clinical and translational investigator with an active research portfolio in pulmonary complications of immunosuppressive disorders as well as cardiopulmonary complications of sickle cell disease.

Dr. Ognibene has been involved with ACTS since its inception, and has worked closely with NIH Clinical Center Director, John I. Gallin, M.D. (former ACTS board member and former federal/NIH liaison for ACTS), on a number of CTSA initiatives in which the NIH Clinical Center was a partner. Dr. Gallin has been a major proponent of the ACTS at the NIH, and with his guidance and mentorship Dr. Ognibene hopes to continue to further strengthen the relationships he has established.

Continue reading for Dr. Ognibene’s answers to our ACTS Leadership Profile Questionnaire.

ACTS Trainee Profile: Kelly Birdwell, MD, MSCI

Kelly Birdwell, MD, MSCI, Assistant Professor of Medicine, Vanderbilt University Medical Center

Through my Translational Scholar Career Award in Pharmacogenomics and Personalized Medicine (K23) funded by the National Institute of General Medical Sciences (NIGMS), I study the complications of transplant immunosuppression in kidney transplant recipients using pharmacogenomics.

After completing internal medicine residency at the University of Colorado Health Sciences Center and nephrology fellowship at Vanderbilt University Medical Center, I became fascinated with kidney transplantation, an intervention that improves both quality of life and survival in patients with end-stage kidney disease. I pursued advanced training in patient-oriented research by completing the Master of Science in Clinical Investigation (MSCI) Program and completed an additional fellowship in kidney transplantation. During my training, I came to understand that short-term outcomes in kidney transplantation are excellent,
but long-term outcomes are more limited, including patient survival. With the number one cause of patient death related to cardiovascular complications, I became particularly interested in the metabolic derangements that occurred in kidney transplant recipients, and the role of transplant immunosuppression medications, vital to preventing rejection of the kidney transplant, played.

After joining faculty at Vanderbilt University Medical Center in 2009, I obtained competitive intramural funding to build a prospective cohort of kidney transplant recipients, collecting blood, urine, body composition measurements, and vascular ultrasound studies to understand the metabolic changes occurring in kidney transplant patients over time and how these relate to development of new onset diabetes and cardiovascular events. With receipt of my career development award, I have extended my area of study to include pharmacogenomics. Using Vanderbilt’s de-identified DNA databank and electronic medical record system, I perform genetic association studies of the drug tacrolimus with new onset diabetes after transplant, with the ultimate goal of understanding an individual’s risk of metabolic complications while taking certain immunosuppression. As promising genetic variants are identified, I will validate these in the prospective cohort I have been building over the past several years. These projects have only been possible with the numerous collaborative mentors and colleagues as well as a strong infrastructure provided by Vanderbilt. In addition, I continue to spend about 20% of my time in the clinic, interacting with the patients that drive the questions important for patient-oriented research in kidney transplantation.

As I move forward with the goal of becoming an independent physician scientist, I will continue to build on my pharmacogenomics research base, both in terms of discovery as well as implementation of findings into the clinic. We have already implemented one genetic variant that affects drug dosing for the immunosuppressant tacrolimus, and plan to study how this affects long term outcomes. I am excited to continue my training and research activities through the unique opportunity of patient-oriented research in transplant pharmacogenomics, always with the overarching purpose of improving care for the individual kidney transplant recipient.

Do you know a trainee who should be profiled in a future issue of ACTS Connection? If so, email a 250-word profile and a photograph to twood@actscience.org.

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Washington Update
The ACTS Connection Editors Want Your Feedback

Translational Science News

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News from ACTS

Washington Update

Congress reconvened following the August recess for a brief September legislative session. The primary order of business at this time is passing a short-term Continuing Resolution to keep all federal programs funded at Fiscal Year (FY) 2014 levels, which would avoid a government shut down on October 1st. While Continuing Resolutions are historically straightforward, recent years have seen spending legislation serve as a lightning rod for partisan controversy and election year politics may characterize this debate. Once the September legislative session ends, Congress will again adjourn until after the November elections.

The outcome of the election is expected to influence how the twelve FY 2015 appropriations measures, particularly the Labor-Health and Human Services-Education (LHHS) appropriations bill, move forward. The Chairwoman of the Senate Appropriations Committee, Senator Barbara Mikulski (D-MD), remains committed to advancing the Senate’s appropriations measures and ultimately enacting the bills. The Senate LHHS bill includes a $600 million funding increase for the National Institutes of Health (NIH) and other investments in medical research while the House has yet to produce an FY 2015 LHHS bill. However, if the balance of power in Congress shifts or gridlock remains intense, legislators could pass a Continuing Resolution that extends FY 2014 funding into January, which would allow the incoming 114th Congress to ultimately decide how the FY 2015 appropriations bills are resolved.

Support for medical research is rarely an issue that rises up in town hall meetings and listening sessions during the congressional campaign season. This year though, many legislators are featuring the issue locally. House members, particularly members of the Energy & Commerce Committee, have been holding events in their districts to solicit input on the 21st Century Cures initiative. Their Senate counterparts continue to call attention to new legislation focused on improving how we fund NIH and other federal research programs on an annual basis. Advocates remain optimistic that this continued emphasis on medical research will bode well for both programmatic support and additional funding after the elections when key issues are ultimately addressed.
Management professor Andrew Lo says drug makers are seeing the financial benefits and clinical trials are taking place for other treatments. the ice-bucket money could help scientists "bridge some dry spells they're feeling federal government, says Mary Woolley, chief executive of Research!America. Accelerated level in ALS donations needs to be sustained by research funded by the Institutes of Health (NIH) expects to spend $40 million on amyotrophic lateral sclerosis that its ice-bucket challenge yielded $31.5 million in donations in a recent three-week impact of philanthropy on investment in disease research. An upsurge in donations to the ALS Association's ice-bucket challenge is highlighting from "Drug Trials: The Challenge of Outside Data" Forbes (08/27/14) Miller, Henry I. "Enrichment' of Subjects in Clinical Trials Is Critical New drug development requires "enriching" collaboration among drugmakers, physicians, regulators, and patients, writes Henry I. Miller, the Robert Wesson Fellow in Scientific Philosophy and Public Policy at Stanford's Hoover Institution and the founding director of the Office of Biotechnology at the Food and Drug Administration (FDA). "Enrichment in clinical trials is "the prospective use of any patient characteristic (including laboratory test values) to select subjects in whom detection of an effect is more likely than it would be in an unselected population," Miller notes. Of increasing importance in determining patient eligibility for a clinical trial are biomarkers as indicators of the likelihood that the treatment will be effective. Prognostic biomarkers, for example, are having a significant effect on cancer therapy, as certain drugs have been found to only work on tumors containing the normal version of the KRAS gene. Patients with mutated variants can be excluded from the studies, since the drugs would be ineffective for them. Thus, enrichment helps to spare patients who are unlikely to benefit from exposure to the drug's toxicity and side effects, and it allows researchers to conduct smaller, more-targeted clinical studies to demonstrate efficacy. However, Miller notes that "the benefits of appropriate enrichment in clinical trials can be undone ... by overly risk-averse regulation." Regulators may require much larger studies to demonstrate a drug's safety, and that could lead to high development costs that are difficult to recover. From "NIH Publishes Finalized Policy on Genomic Data Sharing" Forbes (08/27/14) Miller, Henry I. NIH Publishes Finalized Policy on Genomic Data Sharing The National Institutes of Health’s (NIH) final Genomic Data Sharing (GDS) policy will be applicable to all NIH-funded large-scale human and nonhuman projects that produce genomic data, including research performed with the support of NIH grants and contracts and within the NIH Intramural Research Program. "The collective knowledge achieved through data sharing benefits researchers and patients alike, but it must be done carefully," notes NIH's Kathy Hudson. "The GDS policy outlines the responsibilities of investigators and institutions that are using the data and also encourages researchers to get consent from participants for future unspecified use of their genomic data." A central precept of the policy is the expectation that researchers secure the informed consent of study participants for potential future use of their de-identified data for research and sharing. The two-tiered system for providing access to human data founded on data sensitivity and privacy concerns developed under the previous NIH association studies policy will continue. Researchers will be expected to use controlled-access data solely for the approved research, protect data confidentiality, and acknowledge data-submitting investigators in presentations and publications. NIH officials also expect any data-identifying information to certify the data was obtained legally and ethically and that personal identifiers have been deleted. The GDS policy also expects investigators and their institutions to supply basic plans for adhering to the policy as part of funding proposals and applications. From "NIH Publishes Finalized Policy on Genomic Data Sharing" Genetic Engineering & Biotechnology News (08/27/14) Share | Web Link | Return to Top

Drug Trials: The Challenge of Outside Data A clinical drug trial at the National Institutes of Health (NIH) has temporarily halted enrollment after a patient taking the drug outside the trial reported severe hearing loss after infusion. The trial currently has a dozen patients enrolled for the first phase of a trial of cyclodextrin for the treatment of Niemann-Pick type C (NPC), a fatal genetic disease that causes cholesterol to accumulate in cells. However, the Food and Drug Administration (FDA) permits people with fatal diseases for which there is no treatment to apply for "compassionate use" of experimental drugs, so nearly as many patients outside the trial are also receiving cyclodextrin. The drug's maker, Janssen Pharmaceuticals, provides the drug free of charge to patients with NPC who receive FDA permission. NIH's Dr. Forbes D. Porter, who is running the cyclodextrin trial, reported the finding about the outside patient to an NIH institutional review board. The trial is ongoing, but the board asked Porter not to increase any of the patients' doses or enroll any new patients until the board has discussed the issue. Although the potential for hearing loss associated with cyclodextrin was known based on animal studies, it can be challenging when people take experimental drugs when a trial is being conducted. One dilemma is that while the full benefits of taking cyclodextrin will not be known until the trial is complete, NPC is a fatal disease and patients may be willing to take risks, such as possible hearing loss, in exchange for possible benefits. From "Drug Trials: The Challenge of Outside Data" Wall Street Journal (08/22/14) Marcus, Amy Dockser Share | Web Link | May Require Paid Subscription | Return to Top

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Translational Science News

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How to Speed Up Development: Share Work With Rivals, Say Scientists

A study funded by the National Institutes of Health says drug developers should place their early-stage discoveries into an open-source database or pay a fee in order to curb time wasted due to duplicating results. When sponsors purchase an unsuccessful product from another company to repurpose it for a different disease, they typically lose time repeating basic research. The study says universities, drug firms, and clinical research organizations (CROs) should speed up development and save money by sharing their original research. "The timeline for commercialization is much longer than most people think. There is so much turmoil and churn within the process," observes Jerry Thursby, one of the paper's authors. The discoveries of small entities may become lost when they sublicense their inventions to CROs or larger companies capable of affording clinical trials, according to co-author Matthew Higgins. He notes that, "in most cases CROs are contracted for clearly defined tasks versus exploratory development. If a CRO is focused on task X they may very well ignore ancillary discoveries that are outside of the parameters of their contract." The researchers also suggest that patents and inventions intended for eventual therapeutic be incorporated into "an open-source translational research database that complements clinicaltrials.gov." Reporting into the database could be required by journals and for any research that receives federal funding.

From "How to Speed Up Development: Share Work With Rivals, Say Scientists" OutSourcing-Pharma.com (08/21/14) Barry, Fiona

Clinical Trials: Enhancing Data Quality, Encouraging Participation and Improving Transparency

The U.S. Food and Drug Administration (FDA) plans to take several important steps to enhance the collection and availability of data on demographic subgroups in clinical trials, writes Dr. Margaret A. Hamburg, Commissioner of the U.S. Food and Drug Administration. Under the 2012 FDA Safety and Innovation Act, the agency must examine the extent to which medical product applications include data on trial participation, safety, and effectiveness by demographic subgroups. The FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data includes 27 action items designed to improve completeness and quality of demographic subgroup data collection, reporting, and analysis; identify barriers to subgroup enrollment in clinical trials and strategies to encourage greater participation; and improve transparency of demographic subgroup data. The FDA also will publish "Evaluation of Sex-Specific Data in Medical Device Clinical Studies," guidance that was written in response to the fact that certain women are under-represented in some medical-device studies. The guidance includes recommendations to increase study enrollment and analyze data for sex differences.

From "Clinical Trials: Enhancing Data Quality, Encouraging Participation and Improving Transparency" FDA Voice blog (08/20/14) Hamburg, Margaret A.

5 Takeaways From the 21st Century Cures Initiative - Thus Far

The 21st Century Cures initiative, launched by the U.S. House of Representatives Energy and Commerce Committee in May, is focused on speeding up disease cures and medical breakthroughs. The initiative has seen activity that includes four white papers being authored by the committee; 139 organizations responding to the white papers; and 67 innovators, business executives, and government agencies speaking at roundtables. Five main themes have grown out of the process. The first theme is the encouragement of public-private partnerships to accelerate medical research. This includes calls to jointly identify and validate promising biological targets, and for more open communication between industry and regulators in the drug-development process. A second theme is the encouragement of new models for clinical trials, including adaptive clinical trial designs and greater use of surrogate endpoints. A third theme is the leveraging of data that advances medical knowledge and improves patient care. The fourth theme is finding incentives that encourage innovation, such as expedited review for special medical uses and incentives for personalized medicine. The fifth theme is the need for steady, predictable funding for medical research.

From "5 Takeaways From the 21st Century Cures Initiative - Thus Far" FasterCures (08/19/2014)

NIH Chief Keeps Hopes Afloat

Budget restrictions at the National Institutes of Health (NIH) have forced Director Francis Collins and his staff to make critical choices about which programs to support. In December, Collins appointed NIH's first data science officer. The director's office now has a portfolio analysis component that features powerful tools capable of text mining and other types of network assessments across the NIH community. This can be both retrospective and prospective, he noted in an interview. For instance, abstracts that are submitted to meetings can be text-mined to gain insight into emerging areas of concern. Collins said that nearly every pathway now has illnesses associated with it, but most are rare diseases comprising a genetic mutation. He noted, "I would be worried if there is a message out there that basic science with no connection to a disease is somehow less valued, because I don't feel that way at all. That's our future, that's been our future. But I also would be uncomfortable if people who are doing basic science somehow felt that they had lost their purity if they began to connect their research with a disease that fell into the same pathway, where they might be able to make a useful connection." Collins is enthusiastic about translational science, which is why he helped launch the National Center for Advancing Translational Sciences (NCATS). "Every chance I get, I try to make it clear that NCATS is just trying to make sure that we make the most of these discoveries," he said, "not shift the balance of funding."

From "NIH Chief Keeps Hopes Afloat" Nature (08/15/14) Reardon, Sara
NIH Putting in Place Global Rare Diseases Repository

The National Institutes of Health (NIH) is forming an online central data repository to support and accelerate research in rare diseases worldwide. The repository began as a pilot project, dubbed the Global Rare Diseases Patient Registry Data Repository (GRDR) program, that ended in September 2013. The goal is to aggregate standardized, coded, and de-identified patient and clinical data to make it available to researchers so they can conduct new biomedical studies, including clinical trials. The GRDR program, located at NIH's National Center for Advancing Translational Sciences, gathers phenotypic, clinical, and genomic information along with medical images from individuals who participate in rare disease patient registries. The GRDR program includes about 50 diseases that comprise some 3,800 patients in 90 countries. The GRDR program plans to launch its repository in May 2015, and it expects that registry data will be standardized to common formats to be interoperable with one another and with other national databases.

From "NIH Putting in Place Global Rare Diseases Repository" Health Data Management (08/04/14) Slabodkin, Greg

NIH Launches New Program to Find Potential Drug Targets

Officials at the National Institutes of Health (NIH) have launched an initiative to better understand obscure genes that have the potential to be modified by medicines. The project is part of an NIH Common Fund three-year pilot project called illuminating the Druggable Genome (IDG). NIH has awarded $5.8 million to eight institutions in the initial phase of the program. As many as 3,000 genes express proteins that could potentially have their activities altered by medicines, based on genomic information estimates; however, only about 10 percent of these so-called "druggable genes" are targeted by Food and Drug Administration-approved drugs. The IDG program is intended to address this gap by supporting research in four druggable gene families: nuclear receptors, ion channels, protein kinases, and G-protein coupled receptors. Investigators will share what they learn via a public resource and work to develop ways to rapidly identify and describe the genes they explore. The resulting common language would be used across experimental systems, such as individual cells and complex biological models. One of the grants will be used to form a Knowledge Management Center, led by the University of New Mexico, while the remaining grants will support development of technology to understand functions of members of the four protein families.

From "NIH Launches New Program to Find Potential Drug Targets" PharmAllBiz.com (08/02/14)

Grant Opportunities

DeGregorio Foundation Award for Cancers of the Esophagus and Stomach

The DeGregorio Family Foundation for Gastric and Esophageal Cancer is announcing a funding opportunity for gastroesophageal malignancies. According to the foundation, it supports "high quality, innovative, and transformative translational and bench research to improve the understanding of the biology of these diseases, identification of potential novel therapeutic targets, or in the development and evaluation of novel biomarkers for early diagnosis and treatment. Pre-clinical research, basic mechanistic studies, genomic/epigenomic studies, as well as epidemiologic studies may also be supported." The two-year grant includes up to $225,000 in direct funding and $25,000 in indirect funding. Applications are due by Nov. 3, 2014.

From "DeGregorio Foundation Award for Cancers of the Esophagus and Stomach" DeGregorio Family Foundation (08/28/14)

Autism Speaks: Meixner Postdoctoral Fellowships in Translational Research for 2015

Autism Speaks is requesting applications for its Meixner Postdoctoral Fellowship in Translational Research program, which is designed to support well-qualified postdoctoral scientists pursuing training in autism spectrum disorder (ASD) translational research. The program is open to applicants from public or private institutions doing preclinical or clinical research. Applicants should present projects that encompass basic laboratory research and behavioral or biomedical clinical research, and they must include a training plan that includes mentoring in both basic and clinical research environments. Each award will be for a period of two years and will include a competitive stipend. Letters of intent are due by Nov. 12, 2014.


Burroughs Wellcome Fund: Career Awards for Medical Scientists

The Burroughs Wellcome Fund’s Career Awards for Medical Scientists program provides $700,000 in awards over five years for physician-scientists committed to bridge advanced postdoctoral/fellowship training and the early years of faculty service. Proposals must be in the area of basic biomedical, disease-oriented, or translational research. Proposals in health sciences research or involving large-scale clinical trials are not eligible. Candidates should ideally be two years away from becoming an independent investigator, have at least two years or more of postdoctoral research experience, and have a significant publication record. The application deadline is Oct. 1, 2014.

From "Burroughs Wellcome Fund: Career Awards for Medical Scientists" Burroughs Wellcome Fund (08/27/14)

PCORI Offers Up to $90 Million in Funding in Third Call for Large Pragmatic Studies Proposals

The Patient-Centered Outcomes Research Institute (PCORI) on August 18 issued a
third funding announcement under its Pragmatic Clinical Studies initiative. The institute is offering up to $90 million to support studies that address certain comparative questions in health care. PCORI will provide up to $10 million in direct costs for studies that last up to five years. The announcement includes three new topics that need additional research: the comparative effectiveness of medical treatments compared to invasive procedures for patients with asymptomatic carotid artery disease, the comparative effectiveness of surgical options for hip fracture in older patients, and the comparative effectiveness of different types of surgical mesh or non-use of mesh for the repair of pelvic floor dysfunction. Applicants must submit Letters of Intent no later than October 1, and those invited to submit full applications will be notified by October 31.

From "PCORI Offers Up to $90 Million in Funding in Third Call for Large Pragmatic Studies Proposals"
Patient-Centered Outcomes Research Institute (08/18/2014)

NIDDK Central Repositories Non-Renewable Sample Access (X01)

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has issued a funding opportunity announcement that will enable investigators to apply for access to non-renewable samples from one or more major clinical studies. The NIDDK Central Repositories include samples and data from a number of significant clinical studies. Applications for the next cycle are due by Oct. 30, 2014.

From "NIDDK Central Repositories Non-Renewable Sample Access (X01)"
NIH Grants (08/07/14)