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ACTS Leadership Profile: Emma Meagher, MD

Emma Meagher, MD currently serves as Associate Professor of Medicine and Pharmacology at the Perelman School of Medicine at the University of Pennsylvania in Philadelphia, PA. In addition, she is the Program Director of the Masters of Science in Translational Research, Course Director of Pharmacology for the Perelman School of Medicine, Executive Chair of the University of Pennsylvania Institutional Review Board, Associate Vice Provost for Human Subjects Research, Associate Dean for Clinical Research, and Associate Dean for Admissions for the Perelman School of Medicine.



Dr. Meagher graduated with a medical degree from the Royal College of Surgeons in Dublin, Ireland. Her research interests are the development of novel therapeutics in dyslipidemia and the development of educational programs for translational scientists. Her clinical practice focused on cardiovascular risk modification with an emphasis on management of dyslipidemia, hypertension and women's cardiovascular health.

Dr. Meagher's educational interests are in the fields of translational research methodology to graduate, pre and post-doctoral students and novel modalities for education in systems pharmacology to undergraduate medical (UME) students. In this regard, she currently directs the University of Pennsylvania pharmacology curriculum, serves as the Program Director for the Master of Science degree program in Translational Research and Co-I of the Penn Clinical and Translational Sciences Award (CTSA).

Continue reading for Dr. Meagher's answers to our ACTS Leadership Profile Questionnaire.

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ACTS Trainee Profile: Carmen J. Buxó, DrPH, MPH, MSc

Carmen J. Buxó, DrPH, MPH, MSc
Assistant Professor School of Dental Medicine University of Puerto Rico (UPR)



After completing a post-doctoral Master of Science in Clinical Research as an NIH R25 Phase 1 Scholar, I was granted a K99/R00 from the National Institute of Dental and Craniofacial Research (NIDCR). This Award will allow me to gain experience in genetic and nutritional epidemiology to acquire a comprehensive understanding of conducting etiologic studies of oral clefts, which are prevalent in Puerto Ricans. I also have the opportunity to complement K99 with support from the Hispanic Clinical and Translational Research Education and Career Development Phase 2 Award.

The K99 and my formal education in clinical research will contribute to address the issue of diversity within the national scientific workforce. As a Hispanic woman in science, I am aware of the importance to increase the percentage of Hispanic doctoral scientists in the U.S. Only 1.4% of all employed doctoral scientists and engineers are Hispanic women (NSF, 2008). This disparity merits attention if we consider that Hispanics constitute 16.3% of the nation's population and 49.2% of Hispanics are women (NSF, 2013). As part of my contribution to bridge this gap, I plan to conduct future independent research in craniofacial defects to benefit Puerto Ricans and other populations.

During my research pathway I have been eager to seize opportunities I attained an MPH, worked as Research Coordinator, and completed a DrPH. I received a Diversity Supplement to study genetic risk factors of oral clefts in Puerto Ricans under the

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mentorship of Dr. Jeffrey Murray (University of Iowa). I was also awarded support from the Puerto Rico Clinical and Translational Research Consortium for the pilot project.

I am currently an Assistant Professor at the UPR School of Dental Medicine, research committee member of "ROSTRO" Foundation dedicated to children with craniofacial defects in PR, and a happy wife and mother of two wonderful children.

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

Before adjourning their brief September legislative session, Congress passed a continuing appropriations resolution (CR) to keep the federal government operating at Fiscal Year (FY) 2014 funding levels through December 11th, 2014. After the House approved the measure 319 to 108, the Senate followed suit with a 78 to 22 vote in favor of adopting the CR. In votes that were not party-line, a mix of Republicans and Democrats in both chambers respectively supported and opposed the measure. This action ensures that clinical and translational research programs can operate without the challenges of a stoppage or steep cut in funding, but uncertainty remains as long as FY 2015 appropriations remains unfinished.

The president requested funding from Congress for combat operations and Ebola-related public health activities. Due to the fact that the CR included these provisions as well as maintained financial support for all other federal programs, the president signed the measure into law with little fanfare.

With the House of Representatives reluctant to mark up an FY 2015 Labor-Health and Human Services-Education (LHHS) appropriations bill for political reasons, Democrats in the minority on the House LHHS Appropriations Subcommittee decided to release their own version of the annual spending measure (H.R. 5464). While the proposal put forward by the Democrats is unlikely to be advanced by the Republican-controlled House, and thus will not include an accompanying Committee Report or report language, the bill could serve as an important indicator of House Democratic spending priorities moving into the pivotal negotiations on FY 2015 appropriations. Both the House Democrat's proposal and the FY 2015 LHHS Appropriations Bill that is currently being advanced by the Senate include meaningful funding increases for medical research and patient care activities. Under the proposals, the Agency for Healthcare Research and Quality is essentially level-funded while the National Institutes of Health receives funding increases of approximately \$600 million (Senate) and \$700 million (House). It is expected that if congress can complete FY 2015 LHHS appropriations, clinical and translational research programs should due fairly well, particularly when considering the larger context of tight spending restrictions.

During the September legislative session and shortly thereafter, key legislators from both parties expressed an interest in completing the unfinished FY 2015 appropriations bills during the lame duck session after the November elections. However, it is expected that the outcome of the elections will largely influence how the FY 2015 appropriations process proceeds at the end of the year. If control of the Senate switches parties, it's possible the 113th Congress will hold off on FY 2015 appropriations and allow the incoming 114th Congress to take final action early next year.

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CR Forum Top 10 Clinical Research Achievement Awards Call for Nominations

The Clinical Research Forum is pleased to announce the call for nominations for its annual Top 10 Clinical Research Achievement Awards honoring outstanding accomplishments in clinical research published in 2014. This national competition seeks to identify major advances resulting from the nation's investment in research to benefit the health and welfare of its citizens.

The Forum is a nonprofit organization dedicated to providing national leadership in clinical research. Its mission is to generate support for clinical research and promote

understanding of its impact on health and healthcare delivery. Members are among the nation's most prestigious academic medical centers and health systems.

We invite you to nominate outstanding research projects that:

- represent innovation, creativity and scientific advancement,
- contribute to the understanding of human disease and/or human physiology; and/or
- demonstrate impact on the prevention, diagnosis and/or treatment or increased understanding of the disease state.

New this year, is an on-line submission process for nominations. For details regarding eligibility criteria, nomination/submission process and for access to the link for online submissions go to [Call for nominations](#). The deadline for submissions is **January 9, 2015**.

Winning projects will be recognized at the Clinical Research Forum Annual Meeting in Washington, D.C., April 16-17, 2015. The top accomplishment will be honored with the Herbert Pardes Clinical Research Excellence Award, which has a monetary component. Other monetary prizes will also be awarded. A representative investigator from selected study teams will present their work during the meeting. Study summaries will be included in materials prepared for distribution to the U.S. Congress as part of an effort to encourage continued investment in clinical research.

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The ACTS Connection Editors Want Your Feedback

ACTS Connection Editor, Dr. Satish R. Raj, MD, MSCI, and Associate Editor, Dr. Quinn Wells, MD, PharmD, MSCI, are interested in hearing about ways that *ACTS Connection* could provide even more value to our readers.

Please feel free to email Dr. Raj or Dr. Wells with your comments or suggestions.

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Translational Science News

NIH Funds Next Phase of Tissue Chip for Drug Screening Program

The National Institutes of Health (NIH) is supporting the next phase of its Tissue Chip for Drug Screening program, which aims to improve the prediction of drug safety and effectiveness. The program, led by the National Center for Advancing Translational Sciences (NCATS), will provide \$17 million in 2014 to 11 institutions. The program's researchers will collaborate to refine existing 3-D human tissue chips and combine them into an integrated system that imitates functions in the human body. The tissue-chip systems can be used for experiments that scientists cannot conduct on people, and they may provide information on disease progression that could lead to the development of new therapies. "NCATS aims to get more treatments to more patients more efficiently," said NCATS Director Christopher P. Austin. "That is exactly why we are supporting the development of human tissue chip technology, which could be revolutionary in providing a faster, more cost-effective way of predicting the failure or success of drugs prior to investing in human clinical trials." The Tissue Chip for Drug Screening initiative is a collaboration between the NIH, Defense Advanced Research Projects Agency, and U.S. Food and Drug Administration.

From "NIH Funds Next Phase of Tissue Chip for Drug Screening Program"
NIH News (09/23/14)

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ACT for NIH Seeks Significant Funding Increase to Enhance Life-Saving Medical Research

A new national campaign is underway seeking to significantly increase funding for the National Institutes of Health (NIH). ACT for NIH: Advancing Cures Today, a nonpartisan initiative, is working to bring patients, scientists, advocates, and legislators together to restore NIH's budget and renew the United States' commitment to medical innovation and scientific research. After adjusting for inflation, NIH currently receives about 25 percent less funding than it did in 2003, and many research proposals are not funded. "Medical research in the United States is in crisis," said Pat White, president of ACT for NIH and former Associate Director for Legislative Policy and Analysis at NIH. "Basic scientific discovery funded by NIH leads to new treatments for patients facing life-threatening illnesses. We are missing critical opportunities to discover cures and therapies for diseases like cancer, Alzheimer's, heart disease, diabetes, and countless other conditions." The issues at stake include advancing cures for diseases like cancer and mental illness, employment and other economic growth aided by NIH funding, and national security. In addition to White, the group is led by an Advisory Committee that includes David Baltimore, Ph.D., President Emeritus, California Institute of Technology; Ronald DePinho, M.D., President, The University of Texas MD Anderson Cancer Center; Jennifer Doudna, Ph.D., Professor, University of California, Berkeley; Bernadette Gray-Little, Ph.D., Chancellor, University of Kansas; Michael Milken, Medical Research Innovator and Public Health Advocate; Ronald Petersen, M.D., Ph.D., Director, Mayo Alzheimer's Disease Research Center, and Professor of Neurology, Mayo Clinic College of Medicine.

From "ACT for NIH Seeks Significant Funding Increase to Enhance Life-Saving Medical Research"
News-Medical.Net (09/24/14)

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Health Researchers Will Get \$10.1 Million to Counter Gender Bias in Studies

The National Institutes of Health (NIH) is seeking to curb gender bias in laboratory research by distributing \$10.1 million in grants to more than 80 scientists studying a variety of subjects, including migraines, stroke, and immune responsiveness to vaccines. The researchers will use the funds to include more women in clinical trials and ensure cell lines and laboratory animals are representative of both genders. Additionally, the money will be used to assess gender differences in the resulting data. Janine Austin Clayton, associate director for women's health research at NIH, says: "What we are after is to transform how people think about science and therefore transform how science is done." Women at present are not sufficiently represented in many clinical trials of new drugs and medical devices. One concern with laboratory animals is that the hormonal cycles of female animals can add variability to study results. Abraham A. Palmer, an associate professor of human genetics at the

University of Chicago, says, "If we can understand the mechanisms by which the sex differences might manifest, ultimately we may find different treatments are more effective for one sex or the other."

From "Health Researchers Will Get \$10.1 Million to Counter Gender Bias in Studies"
New York Times (09/23/14) P. A16 Rabin, Roni Caryn

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Dems Push to Ease Budget Caps on Medical Research

U.S. Reps. Rosa DeLauro (D-Conn.) and Bill Higgins (D-N.Y.) have introduced legislation to increase funding for the National Institutes of Health (NIH). The Accelerating Biomedical Research Act would set a new budget cap adjustment under which any NIH funding exceeding \$29.9 billion would trigger a budget cap increase. If enacted, the bill would lead to a 10 percent increase in appropriations for the NIH the first two years and a 5 percent in later years. "Failure to invest in health research and disease prevention results in huge costs to our health, society, economy, and knowledge itself. Congress must stop forcing the NIH to do more with less," said DeLauro in a statement. Higgins called on Congress to look at medical research as a national priority, noting that their bill "will start to return vital funding to the NIH and continue our pursuit to find better treatments and cures for so many debilitating diseases." A fiscal 2015 appropriations bill recently introduced by DeLauro and others to fund the Departments of Labor, Health and Human Services, and Education would provide \$778 million in additional funding to NIH.

From "Dems Push to Ease Budget Caps on Medical Research"
The Hill (09/19/14) Shabad, Rebecca

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Promising Research Can't Stall for Lack of Funding

Medical research organizations are pushing for Congress to increase funding for research that can encourage private-sector innovation. In a piece for the Huffington Post, Judith A. Salerno, president and CEO of Susan G. Komen, and Mary Woolley, president and CEO of Research!America, assert that well-funded federal agencies are essential to disease response, as are partnerships between public and private sectors. "In addition, federal research agencies like the [National Institutes of Health] and the National Science Foundation fuel scientific discovery at academic institutions, providing the resources that are critical to supporting small- and large-scale projects that could lead to promising new therapies and medical devices." Scientists at UC Berkeley are working to grow human organ tissues on tiny chips, which could eventually replace years animal or human testing. Funding by the Cures Acceleration Network, which is overseen by the National Center for Advancing Translational Sciences, is aiding this research. The National Institutes of Health, Novartis, and the Banner Alzheimer's Institute are also testing drugs to prevent Alzheimer's in genetically at-risk individuals. Salerno and Woolley write that such research projects are threatened by loss of support, and they encourage Congress to increase funding for medical research.

From "Promising Research Can't Stall for Lack of Funding"
Huffington Post (09/12/14) Salerno, Judith A.; Woolley, Mary

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CORD Urges Ministers of Health to Adopt Proven Model for Improved Access to Treatments for Rare Disorders

The Canadian Organization for Rare Disorders (CORD) is calling on the nation's provincial and territorial ministers of health to adopt solutions that would help provide life-extending and life-saving therapies to Canadians suffering from rare disorders. A rare disease is usually defined as a disorder that affects fewer than one in 2,000 people, and there are more than 7,000 different types of rare diseases. Only half of the rare-disease drugs available to patients in the United States or Europe are approved in Canada, and of those, only half are funded by public drug plans. CORD is proposing a managed-access program of multiple stakeholders, by which patients could have reimbursed access to new therapeutics, as well as ongoing monitoring for safety, efficacy, and cost-effectiveness. The CORD proposal offers a practical model based on international and Canadian experience, with support from the rare-disease community. This is the result of research and consultation with stakeholders conducted since 2005.

From "CORD Urges Ministers of Health to Adopt Proven Model for Improved Access to Treatments for Rare Disorders"
Canada NewsWire (09/24/14)

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High Tech Town Hall Charts Path to Reform Drug Development, Spur Innovation

The 21st Century Cures initiative is encouraging tech and drug companies, patient groups, and hospital systems to discuss barriers to biomedical innovation and how to overcome them. A theme that has emerged is that innovation should involve collaboration, with government investment in private industry. One idea for advancing this "team-based" innovation is to update Food and Drug Administration (FDA) regulations to harness the full potential of modern technologies so that customized cures can reach patients faster and less expensively. To achieve this, one recommendation is to expand the FDA's current accelerated approval pathway, based on surrogate endpoints or biomarkers that suggest early on whether the drugs are likely to deliver clinical benefits. Patients also may be made partners in advancing medical research by allowing them to own and control their own health data, with appropriate privacy protections, while still allowing for the pooling and analysis of de-identified clinical trial data. In addition, leaders should ensure a stable source of funding for basic medical research, possibly by pegging National Institutes of Health funding to GDP growth. Policymakers also could work to develop robust incentives for innovators working on treatments for diseases like Alzheimer's.

From "High Tech Town Hall Charts Path to Reform Drug Development, Spur Innovation"
Morning Consult (09/09/14) Howard, Paul

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Mayo Clinic Hopes Watson Can Find More Patients for Its 8,000 Clinical Trials

Starting next year, the Mayo Clinic will partner with IBM's Watson data analytics platform to match patients to clinical trials. This will introduce what IBM calls cognitive computing into clinical use, specifically for cancer studies. "In an area like cancer--

where time is of the essence--the speed and accuracy that Watson offers will allow us to develop an individualized treatment plan more efficiently so we can deliver exactly the care that the patient needs," said Steven Alberts, chair of medical oncology at Mayo Clinic. Mayo Clinic conducts over 8,000 human studies at one time, and officials say that Watson's computing will help sift through trials to help more patients get matched up with the most promising options. Many healthcare trials go uncompleted due to a lack of sufficient enrollment. Only 3 percent of all patients take part in studies across the United States, but the Mayo Clinic hopes to boost its rate to 10 percent. Under the partnership, IBM will design a version of Watson specifically for the Mayo Clinic and will "train" it to analyze patient records and clinical trial criteria to determine appropriate trial matches for patients.

From "Mayo Clinic Hopes Watson Can Find More Patients for Its 8,000 Clinical Trials"
MedCity News (09/08/14) Verel, Dan

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BGI, Imperial College, Waters Ink Deal to Accelerate Translational Medicine

BGI, Imperial College of London, and Waters have agreed to a partnership intended to accelerate translational medicine. The organizations will use research and development projects that incorporate omics-related and clinical applications to develop comprehensive standards and approaches for human omics testing and data analysis. According to Vince Gao, head of BGI Health, the collaboration expects to apply research to the prediction and prevention of diseases such as cancer and cardiovascular disease. The work will focus on biomarker detection and multidimensional data to translate, accumulate, and update omics, clinical, and health knowledge.

From "BGI, Imperial College, Waters Ink Deal to Accelerate Translational Medicine"
GenomeWeb News (09/11/2014)

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Grant Opportunities

Stand Up To Cancer-American Cancer Society Lung Cancer Translational Research Dream Team

The American Association for Cancer Research, on behalf of Stand Up To Cancer and the American Cancer Society, is calling for submissions of ideas for a translational cancer research project that addresses critical problems in lung cancer and positively impacts patients in the near future. Ideas should focus on therapeutic interventions for lung cancer, and they should provide near-term patient benefit through investigation by a multidisciplinary, multi-institutional, synergistic Dream Team of experts. The research should involve new immunological approaches, and proposals should include plans for how the work will be translated into the clinic. The Lung Cancer Dream Team will be awarded up to \$20 million over the three-year term of the grant. Letters of intent are due by Nov. 5, 2014.

From "Stand Up To Cancer-American Cancer Society Lung Cancer Translational Research Dream Team"
American Association for Cancer Research (09/26/14)

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International Society for CNS Clinical Trials and Methodology 2015 New Investigator Award

The International Society for CNS Clinical Trials and Methodology has announced the 2015 New Investigator Award. The award will be given to promising new investigators in the society's wide range of methodological, regulatory, and substantive programmatic interests. The award will be given to one international and four domestic applicants, and the appointments will last for a year. Eligible candidates include early career academic or industry professionals in relevant disciplines and positions; research fellows in CNS disciplines; postdoctoral trainees in biostatistics, epidemiology, pharmacy, nursing, public health, and social/behavioral sciences; and translational scientists with interest in biomarker-based approaches to treatment development. Applications are due by Nov. 10, 2014.

From "International Society for CNS Clinical Trials and Methodology 2015 New Investigator Award"
International Society for CNS Clinical Trials and Methodology (09/26/14)

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NIAID Clinical Trial Planning Grant (R34)

The National Institute of Allergy and Infectious Diseases (NIAID) has issued a funding opportunity announcement (FOA) seeking applications that propose the complete planning, design, and preparation of the documentation necessary for implementation of investigator-initiated clinical trials. The trials must be hypothesis-driven, milestone-defined, related to the research mission of the NIAID, and considered high priority by the Institute. Awards made under the FOA will support clinical trial activities including establishment of the research team, identification of collaborators and enrollment sites, design of the study, development of the complete clinical protocol, development of the statistical analysis plan, development of milestones, development of a data and safety monitoring plan, development of training materials and training plans for study staff. Applications are due by Jan. 13, 2015.

From "NIAID Clinical Trial Planning Grant (R34)"
NIH Grants (09/26/14)

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APS/SPR Mary Ellen Avery Neonatal Research Award

The Mary Ellen Avery Neonatal Research Award, from the American Pediatric Society and the Society for Pediatric Research, recognizes the lifetime achievement of a pediatric investigator who has made important contributions to neonatal health through basic or translational research. Nominees must be pediatric investigators with a sustained record of excellence as a neonatal health investigator. One award will be made each year, and along with it will be a \$1,000 honorarium, a plaque, travel expenses, and registration for Pediatric Academic Societies meeting. Nominations are due by Nov. 11, 2014.

From "APS/SPR Mary Ellen Avery Neonatal Research Award"
American Pediatric Society/Society for Pediatric Research (09/26/14)

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The Milstein Medical Asian American Partnership Foundation Fellowship Award in Translational Medicine

The Milstein Medical Asian American Partnership Foundation has announced its Fellowship Award in Translational Medicine. The program seeks to build a lasting partnership between the United States and Asia through training of future Chinese academic leaders and to encourage long-term collaborations between the two regions. The award, open to Chinese medical researchers who conduct translational research, will support one year of training at a prominent sponsoring institution in the United States. In all, the award includes \$60,000 for one fellow and an accompanying \$25,000 for the sponsoring U.S. institution. Applications are due by Nov. 1, 2014.

From "The Milstein Medical Asian American Partnership Foundation Fellowship Award in Translational Medicine"
MMAAP Foundation (09/25/14)

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CTSA Program Funding Opportunity Now Available

The National Center for Advancing Translational Sciences (NCATS) has announced a new funding opportunity for the Clinical and Translational Science Awards (CTSA) program. This program involves a national network of medical research institutions that collaborate to transform clinical and translational science. The medical research centers that make up the CTSA network support high-quality research and innovation in training, collaboration, and methodology. Applications for the new funding opportunity are due Jan. 15, 2015. There is new emphasis on aligning the CTSA program with NCATS' overall goals, building a national network to achieve translational science goals, and training a new generation of clinical and translational scientists. "The evolved CTSA's will better enable the realization of the program's full potential for transforming clinical and translational science with the ultimate goal of improving human health," said Dr. Petra Kaufmann, director of NCATS' Division of Clinical Innovation.

From "CTSA Program Funding Opportunity Now Available"
National Center for Advancing Translational Sciences (09/12/2014)

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