Translational Science 2015 Program
Thursday, April 16th, 2015

<table>
<thead>
<tr>
<th>Session</th>
<th>Time</th>
<th>Room</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH Tour</td>
<td>7:30am – 12:30pm</td>
<td>Offsite- NIH Campus</td>
</tr>
<tr>
<td>Advocacy Training</td>
<td>8:00am – 9:00am</td>
<td>Congressional A/B</td>
</tr>
<tr>
<td>Photo on Capitol Steps (For those participating in Hill Visits)</td>
<td>10:00am – 10:30am</td>
<td>Offsite- US Capitol</td>
</tr>
<tr>
<td>Hill Visits</td>
<td>10:30am – 1:00pm</td>
<td>Offsite- Senate and House</td>
</tr>
<tr>
<td>Predoctoral and Postdoctoral Mock Study Sections</td>
<td>2:00pm – 4:30pm</td>
<td></td>
</tr>
<tr>
<td>CR Forum</td>
<td>3:00pm – 7:30pm</td>
<td>Palladian Ballroom</td>
</tr>
<tr>
<td>Joint Opening Plenary with CR Forum and Awards Presentation</td>
<td>5:00pm – 6:30pm</td>
<td>Regency Ballroom</td>
</tr>
</tbody>
</table>

Robert M. Califf, MD, Deputy Commissioner, Medical Products and Tobacco, FDA
“Perspective of the National Center for Advancing Translational Science on Opportunities in Translational and Clinical Research and Training”
Petra Kaufmann, MD, MSc, Clinical Innovation Director, National Center for Advancing Translational Sciences (NCATS)

Joint Poster Reception with CR Forum               | 6:30pm – 7:30pm    | Poster Hall                         |

Friday, April 17th, 2015

<table>
<thead>
<tr>
<th>Session</th>
<th>Time</th>
<th>Room</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breakfast</td>
<td>7:00am – 8:00am</td>
<td>Regency Gallery</td>
</tr>
<tr>
<td>CR Forum</td>
<td>7:00am – 11:30am</td>
<td>Palladian Ballroom</td>
</tr>
<tr>
<td>ACTS Annual Business Meeting</td>
<td>7:15am – 7:45am</td>
<td>Regency Ballroom</td>
</tr>
<tr>
<td>Plenary Session and Awards Presentation</td>
<td>8:00am – 9:30am</td>
<td>Regency Ballroom</td>
</tr>
</tbody>
</table>

“Scaling & Entrepreneurship”
Geoffrey Smith, JD, Managing Director, Mars Grand Challenge Ventures
Entrepreneurs work hard to scale initial ideas into thriving enterprises. How important is scale in achieving success? Do the laws of scaling observed in biology and social networks provide any lessons for entrepreneurs? This talk will explore various paths to entrepreneurial success.

“Personalized Therapy for Advanced Non-small Cell Lung Cancer: From the Battle Trials to the Master Protocol”
Roy Herbst, MD, PhD, Ensign Professor of Medicine, Professor of Pharmacology, Chief of Medical Oncology, Director, Thoracic Oncology Research Program, Associate Director for Translational Research, Yale Comprehensive Cancer Center, Yale School of Medicine

Lung cancer is the number one cause of cancer death in the United States. Over the last twenty years, the therapy of this disease has improved with the advent of biopsy-driven personalized therapy approaches such as the BATTLE trials and the elucidation of specific driver mutations. Additionally, the recent incorporation of immunotherapy into lung cancer treatment has created a new paradigm for this disease and is accelerating the pace of biomarker development. This has led to newer approaches such as the lung cancer master protocol (LungMAP) to match the right patient to the right drug at the right time. In this lecture progress in this field will be highlighted in the setting of translational research advances.

Career Development: A Focus on K to R Mentoring  9:45am – 11:15am

The session will focus on some of the challenges facing the mentor and the mentee associated with the transition from career development awards to independent research status (PI role on a R01 or similar grant) and ways to overcome them. The session is aimed at early investigators aiming to write an R grant and the program directors and mentors that support their development into independent investigators.

Chairs:
Emma A. Meagher, MD, Senior Associate Dean, Director Translational Research Education, University of Pennsylvania Perelman School of Medicine
Ellie Schoenbaum, MD, Director, Medical Student Research, Clinical Research Training Program and PhD in Clinical Investigation; Co–Program Director for Research, Education and Training of the Harry and Muriel Block Institute for Clinical and Translational Science, Albert Einstein College of Medicine

Confirmed Speakers:
“Step by Step Towards Independence”
Melissa D. Begg, ScD, Vice Provost for Educational Programs, Professor of Biostatistics, and Co-Director, Irving Institute for Clinical and Translational Research, Columbia University

“Successfully Transitioning from K to R”
Doris Rubio, PhD, Professor of Medicine, Biostatistics and Clinical and Translational Science, Co-Director, Institute For Clinical Research Education, University of Pittsburgh School of Medicine

“Understanding Career Success and Contributing Factors for Clinical and Translational Investigators”
Georgeanna Robinson, EdD, Assistant Director, Institute For Clinical Research Education, University of Pittsburgh School of Medicine

Education Administrators Networking  9:45am – 11:15am

This session will provide an opportunity for non-faculty education and career development administrators to share best practices, and mentor one another. This session will consist of two portions. In the first half, speakers include Cecilia Patino-Sutton, MD, MEd, PhD presentation on Southern California Clinical and Translational Science Institute’s Community Mentoring Program for Young Clinical Translational Researchers and Susan Pusek, MPH, MS presentation...
on North Carolina Translational & Clinical Science Institute’s best practices in education and training. The second portion of the session will focus on roundtable discussions on topics relevant to education administrator such as evaluation, mentoring, innovation in training programs, etc.

Chair:
Jennifer McKanry, MS, Project Manager, Curriculum and Evaluation, Clinical Research Training Center, Washington University in St. Louis School of Medicine

Confirmed Speakers:
“Community Mentoring Program for Young Clinical Translational Researchers: The Pilot Phase”
Cecilia Patino-Sutton, MD, MEd, PhD, Director of Education, Southern California Clinical and Translational Science Institute (SC CTSI), University of Southern California, Los Angeles

“A Model for Developing, Evaluating, and Disseminating Best Practices in Education and Training”
Susan N. Pusek, MPH, MS, Director of Education Program, North Carolina Translational and Clinical Science Institute (NC TraCS), University of North Carolina, Chapel Hill

The Inside Story of Monoclonal Antibodies | 9:45am - 11:15am

Most antibodies are unable to directly cross cell membranes, but mAb 3E10 is a rare lupus anti-DNA antibody that was serendipitously discovered to penetrate living cells and localize to the nucleus without causing any apparent cytotoxicity. An engineered single chain variable fragment of mAb 3E10 (3E10 scFv) with enhanced cell penetration has been developed as a therapeutic delivery system with multiple clinical applications that include:

- Protein transduction of a heat shock protein, Hsp70, for the treatment of stroke and myocardial infarction.
- Transduction of therapeutic anti-cancer antibodies to intracellular and intranuclear sites as bispecific, single chain Fv fragments.
- Targeted therapy for DNA repair-deficient malignancies by using 3E10 scFv to inhibit DNA repair.

This session will review the discovery of mAb 3E10, the many potential uses of 3E10 in molecular therapy, and future goals in the development of cell-penetrating antibody-based therapy.

Chairs:
Keith Colburn, MD, Head, Medicine, Rheumatology & Immunology Division; Professor of Internal Medicine and Rheumatology; Professor of Basic Sciences, Loma Linda University Medical Center

Confirmed Speakers:
“The Serendipitous Discovery of 3E10 as a Cell-Penetrating Antibody and Recognition of its Therapeutic Potential”
and
“Applications of 3E10 scFv in Cancer Therapy”
James E. Hansen, MD, Assistant Professor of Therapeutic Radiology, Yale School of Medicine

“3E10 Fv-Hsp70 Therapy in a Rat Stroke Model”
Robert N. Nishimura, MD, Professor of Neurology, University of California, Los Angeles, School of Medicine

“3E10 Fv-Hsp70 Therapy in a Rabbit Myocardial Infarction Model”
Missag H. Parseghian, PhD, Chief Scientific Officer, Rubicon Biotechnology

Introduction to Intellectual Property Concepts in Translational Science | 9:45am – 11:15am
Intellectual property (IP) includes creations of the mind such as ideas, information, perceptions, and expressions of ideas. Translational scientists frequently generate IP, yet they are often unaware of the commercial potential of such creations, nor of the need to legally protect rights to IP. This session will use case studies to introduce several types of IP that do not fit the typical model of inventions, including risk prediction tools and software. Patents, trade secrets, trademarks, and copyrights will be reviewed as methods to protect IP, and issues related to copyright and patent infringement, inventorship vs. authorship, open-source vs. for-profit, and liability will be discussed.

Chair:
Susan M. Perkins, PhD, Associate Professor, Department of Biostatistics, Indiana University School of Medicine

Confirmed Speakers:
“Introduction to Concepts Related to Intellectual Property”
Leah J. Welty, PhD, Professor, Department of Preventative Medicine, Northwestern University Feinberg School of Medicine

“Patenting and Commercializing a Multi-Biomarker Risk Model for the Risk Stratification of Pediatric and Adult Patients with Septic Shock”
Christopher J. Lindsell, PhD, Professor and Associate Dean for Clinical Research, Department of Emergency Medicine, University of Cincinnati College of Medicine

Anantha Shekhar, MD, PhD, Professor and Associate Dean of Translational Research, Director of the Indiana CTSI, Indiana University School of Medicine

Scholar Networking Meeting with Federal Training Partners 9:45am – 11:15am
Come and meet with program officials to exchange ideas, advice, and information about research projects and grant opportunities. This year there will be representatives from the Food and Drug Administration (FDA), Patient-Centered Outcomes Research Institute (PCORI), the Agency for Healthcare Research and Quality (AHRQ), the Substance Abuse and Mental Health Services Administration (SAMHSA), in addition to the NIH. Representative program officers will be available for 90 minutes for scholars to engage with directly and discuss individual career development plans and grant application strategies.

Confirmed Participants:
Ming Lei, PhD, Deputy Director, Center for Cancer Training, National Cancer Institute, National Institutes of Health (NIH)
Diane Bild, MD, MPH, Senior Program Officer Clinical Effectiveness Research Program, Patient-Centered Outcomes Research Institute (PCORI)
Kishena Wadhwani, PhD, MPH, Director, Division of Scientific Review (DSR) Office of Extramural Research, Agency for Healthcare Research and Quality (AHRQ)
Chekesha S. Clingman, PhD, MBA, Special Assistant, CDR USPHS Office of Translational Sciences, U.S. Food and Drug Administration (FDA)
Kimberly Jeffries Leonard, PhD, Deputy Director, Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration (SAMHSA)

Concurrent Predoctoral and Postdoctoral Oral Presentations 11:30am – 1:00pm
CR Forum Top Ten Awards Presentation 11:30am – 1:00pm  Palladian Ballroom
Lunch (Lunch Cart Available) 1:00pm – 2:30pm
TL1 Pre-doctoral Lunch at Marriott Wardman Park
CR Forum Meeting 1:00pm – 7:00pm  Palladian Ballroom
**How to Write a Successful K24 Grant to Support Your Mentoring**

2:30pm – 4:00pm

Did you know that the NIH has grants to support mentoring? A Mentoring K grant is an excellent way to get support for the mentoring you are already doing! In this interactive session, an experienced K24 recipient and NIH Review Officer will help you shape a strategy for your initial K24 application as well as renewal. The NIH Mid-career Investigator Award in Patient-oriented Research (K24) is a grant mechanism that protects the time of associate professor level clinician investigators who mentor junior investigators in patient oriented research (POR). Are you an Associate Professor level faculty performing POR? A K24 might be right for you. Learn what reviewers are looking for in mentoring awards, common weaknesses to avoid, and how to make your application successful.

Chair:
Ellen W. Seely, MD, Vice Chair, Faculty Development, Department of Medicine, Director of Clinical Research Endocrinology, Diabetes and Hypertension Division, Brigham and Women's Hospital and Professor of Medicine, Harvard Medical School

Confirmed Speakers:
“Tips to Writing A Successful Mentoring Grant and Renewal: An Applicant Perspective”
Ellen W. Seely, MD, Vice Chair, Faculty Development, Department of Medicine, Director of Clinical Research Endocrinology, Diabetes and Hypertension Division, Brigham and Women's Hospital and Professor of Medicine, Harvard Medical School

“The Review Process of a Mentoring Application: A NIH Scientific Review Officer Perspective”
Barbara A. Woynarowska, PhD, Scientific Review Officer, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

**Writing a Successful K**

2:30pm – 4:00pm

The “K” Kiosk offers details on NIH funding opportunities for post-doctoral scholars and junior faculty which can facilitate their paths to sustainable careers in translational research. In this session, the speakers will bring their experience and expertise to explain the strategy and techniques required for writing a successful “K” award.

Chair:
Frederick P. Ognibene, MD, MCCM, FACP, Deputy Director, Educational Affairs and Strategic Partnerships, NIH Clinical Center (CC); Director, Office of Clinical Research Training and Medical Education, National Institutes of Health

Confirmed Speakers:
“What are K Awards? Which is Right for You?”
Marie Gelato, MD, Professor, Department of Medicine, Stony Brook University

“Career Development Section: The Cornerstone of the K”
Paula Gregory, PhD, Director of Faculty Development; Professor, Department of Genetics, Louisiana State University Health Sciences Center, New Orleans

“Effective Use of Review Comments: Getting it Funded”
Melissa Harris, PhD, Postdoctoral Fellow, National Human Genome Research Institute, NIH

**How to Write an R Grant**

2:30pm – 4:00pm

Are you about to write your first R01? Want to know how it works? This training session is a short introduction to the concepts Dr. Freishtat teaches in his national grantsmanship workshops.
Chair/Speaker:
Robert J. Freishtat, MD, MPH, Associate Chief for Academic Affairs, Division of Emergency Medicine, Children’s National Health System, Associate Professor of Pediatrics, Emergency Medicine, and Integrative Systems Biology
George Washington University School of Medicine and Health Sciences

Resonant Leadership Workshop  2:30pm – 4:00pm

The workshop will be geared to investigators who have aspirations to serve in leadership roles including medical director, division chief, department chair, dean, and other positions. The session will provide tangible examples of goal directed leadership activities and tools to both increase one’s chances of obtaining these leadership positions, but more importantly, prospering and succeeding in these roles. Dr. Annie McKee is a bestselling author and advisor to top global leaders, from CEOs of Fortune 500 companies to government officials in South Africa. She is co-author of the book Primal Leadership, that explores emotional intelligence and how to develop emotional intelligence leadership competencies to inspire and guide. Annie McKee will engage the audience in practical and interactive exercises to help participants learn what resonant leaders do to build strong teams, a resonant culture, and a climate that fosters innovation.

Chair:
Carol Merchant, MD, MPH, Program Director, Extramural Career Development Program, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH)

Moderators:
Megha Ramaswamy, PhD, MPH (SCHOLAR), Assistant Professor, Preventive Medicine and Public Health, University of Kansas School of Medicine
Jasjit S. Ahluwalia, MD, MPH, MS, Dean, Rutgers University School of Public Health

Confirmed Speaker:
Annie McKee, PhD, Program Director and Senior Fellow, Chief Leadership Office (PennCLO) & Medical Education, Teaching, Learning, and Leadership Division, Graduate School of Education, University of Pennsylvania

Developing Skills for Effective Communication in Multidisciplinary Team  2:30pm – 4:00pm

This workshop will present different perspectives of leadership experiences and pathways to success, as well as case scenarios that will allow the participants to discuss and practice effective communication strategies. Virtual teams’ issues and challenges of group dynamics will also be discussed.

Chair:
Estela S. Estape, MT, PhD, DHL, Professor, Graduate Department, School of Health Professions, PI & Director of the Post-doctoral Master of Science in Clinical and Translational Research & of Hispanics in Research Capability (HiREC) Endowment Program; Leader, Professional Development Core, PR Clinical & Translational Research Consortium Medical Sciences Campus, University of Puerto Rico

Confirmed Speakers:
“In Pursuit of a Goal”
Estela S. Estape, MT, PhD, DHL, Professor, Graduate Department, School of Health Professions, PI & Director of the Post-doctoral Master of Science in Clinical and Translational Research & of Hispanics in Research Capability (HiREC) Endowment Program; Leader, Professional Development Core, PR Clinical & Translational Research Consortium Medical Sciences Campus, University of Puerto Rico
“Choosing the Team”
Clemente Díaz, MD, Professor, School of Medicine; Associate-Director, Postdoctoral Master of Science in Clinical and Translational Research Program; PI, Hispanics in Research Capability (HiREC) Endowment Program, Medical Sciences Campus, University of Puerto Rico

“Against All Odds”
Bárbara Segarra-Vázquez, MT, DHSc, Dean, School of Health Professions; Associate Director, Post-doctoral Master in Science in Clinical & Translational Research Program; School of Health Professions, Medical Sciences Campus, University of Puerto Rico

“Teamwork to Reach the Goal”
Karen Martinez González, MD, MSc, Assistant Professor, Department of Psychiatry; PI & Director, Center for the Study and Treatment of the Fear and Anxiety, School of Medicine, Medical Sciences Campus, University of Puerto Rico

<table>
<thead>
<tr>
<th>Predoctoral Concurrent Oral Presentations</th>
<th>2:30pm – 4:00pm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparing an F-Award at the Pre-Doctoral Level</td>
<td>4:15pm – 5:45pm</td>
</tr>
</tbody>
</table>

An interactive session presented by PJ Simpson-Haidaris, a faculty member with great experience and success in mentoring PhD and MD-PhD students through the process of writing a pre-doctoral fellowship proposal. The practical tips and pearls will be valuable for NIH F-awards and for other federal or foundation proposals. Hand-out materials will provide take-home resources for students.

Chair/Speaker:
“The First (F) Award? No, F Does Not Mean First but Fellowship!”

PJ Simpson-Haidaris, PhD, Associate Professor of Medicine, University of Rochester; Director, PhD Program in Translational Biomedical Science

Speaker:
Stephen C. Ekker, PhD, Professor of Biochemistry/Molecular Biology, Associate Director, Center for Clinical & Translational Science Predoctoral Programs, Mayo Clinic College of Medicine

| Serendipity in Science | 4:15pm – 5:45pm |

Some of medicine’s most illustrious discoveries have been guided by the researcher’s willingness to embrace and interpret serendipitous findings. Like the discovery of penicillin by Alexander Fleming, even the most carefully planned research is often guided by unexpected clues – but paired with rigorous inquiry, they often lead to important findings. In this session, experts from several fields present and discuss a multi-disciplinary approach to study interaction and signaling across different disease phenotypes. Here the pioneers from various field will not only present their data, but they will also share their pearls in finding unconventional clues that lead them to recent advances - showcasing how “chance” may indeed “favor the prepared mind.”

Chairs:
MingMing Ning, MD, Director, Neurology consultation and Clinical Proteomics Research Center, Massachusetts General Hospital, Harvard Medical School

Confirmed Speakers:
“Inventing the Inventors—From Liquid Battery to Human Disease”
Donald Sadoway, PhD, John F. Elliott Professor of Materials Chemistry, Massachusetts Institute of Technology
“Innovative Technology and Clinical/Translational Research in Proteomics”
Mary Lopez, PhD, Director, BRIMS Center, Thermo Scientific

“Sex, Stroke, and Innovation”
Patricia Hurn, PhD, Vice Chancellor for Research and Innovation; Chief Health Research Officer, University of Texas Health System

Advancing Regulatory Science Training | 4:15pm – 5:45pm
---
This session will explore topics in Regulatory Science, particularly focusing on identifying Regulatory Science core competencies and emerging approaches to address training needs.

The session will:
- Highlight the results of a CTSA Consortium initiated effort developing core competencies to guide training in Regulatory Science
- Discuss the development and launch of a new Regulatory Science Master’s program as a case study for other academic institutions
- Provide an overview of FDAs Regulatory Science workforce needs and FDA supported initiatives to enhance Regulatory Science training

Chair:
Scott Steele, PhD, Director, Government & Academic Research Alliances, Associate Professor, Public Health Sciences, University of Rochester

Confirmed Speakers:
“Developing a Regulatory Science Education Program”
Emma Meagher, MD, Director, Translational Research Training Programs, Associate Dean, Clinical Research, University of Pennsylvania

Scott Steele, PhD, Director, Government & Academic Research Alliances, Associate Professor, Public Health Sciences, University of Rochester

Leslie Wheelock, MS, RN, Director, Office of Scientific Professional Development, Office of the Chief Scientist, Office of the Commissioner, FDA

Effective Community-Engaged Approaches to Improving Community Health and Reducing Health Disparities in Underserved Populations: Are we There Yet? | 4:15pm – 5:45pm
---
This session will provide an overview of community-engaged research (CEnR), an increasingly used approach in which researchers and communities ethically and effectively collaborate to address and reduce health disparities. We will present examples of how CEnR is being translated into services in a way that addresses the unmet mental health needs of underserved populations at the local level. We will conclude with a demonstration from three local examples of how researchers and communities are coming together to build meaningful partnerships and organize to jointly make decisions and achieve transformative action for improving community health and reducing health disparities.

Chair:
Sergio Aguilar-Gaxiola, MD, PhD, Professor of Clinical Internal Medicine, Director, Center for Reducing Health Disparities (CRHD), Director, Community Engagement Program of the Clinical Translational Science Center (CTSC), Co-Director, Latino Aging Research Resource Center, The University of California, Davis, School of Medicine
Confirmed Speakers:

“A Cultural Transformation Model: Increasing Access and Improving Culturally and Linguistically Competent Services and Outcomes to Filipino and Latino Underserved Communities”
Sergio Aguilar-Gaxiola, MD, PhD, Professor of Clinical Internal Medicine, Director, Center for Reducing Health Disparities (CRHD), Director, Community Engagement Program of the Clinical Translational Science Center (CTSC), Co-Director, Latino Aging Research Resource Center, The University of California, Davis, School of Medicine

“HealthStreet: An Innovative Community Engagement Model to Detect Needs and Concerns of Underserved Populations”
Linda Cottler, PhD, MPH, Associate Dean for Research and Planning, College of Public Health and Health Professions, Dean’s Professor and Chair-Department of Epidemiology, College of Public Health and Health Professions and College of Medicine, University of Florida

“The Steps Model: Methods and Metrics for Community-Engaged Research with Underserved Communities”
Alexandra Adams MD, PhD, Professor, Department of Family Medicine, Director, Collaborative Center for Health Equity, and Assistant Director, Community Engagement, Institute for Clinical and Translational Research, University of Wisconsin School of Medicine and Public Health-Madison

Poster Reception 6:00pm – 7:00pm Poster Hall

Saturday, April 18th, 2015

<table>
<thead>
<tr>
<th>Session</th>
<th>Time</th>
<th>Room</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breakfast</td>
<td>7:00am – 8:00am</td>
<td>Regency Gallery</td>
</tr>
<tr>
<td>Plenary Session</td>
<td>8:00am – 9:00am</td>
<td>Regency Ballroom</td>
</tr>
</tbody>
</table>

Dr. Wilson’s talk will focus on the challenges inherent in developing "Big Data" infrastructure for translational research. These challenges include scaling data acquisition from a single patient bed, to a small intensive care unit, and then to an institution-wide data-center. Dr. Wilson will provide examples of research that has benefited from a Big Data approach and consider the costs and potential benefits to healthcare in the United States.

Confirmed Speaker:
Christopher Wilson, PhD, Associate Professor, Center for Perinatal Biology, Loma Linda University

mHealth in Medicine and Biomedical/Translational Research 9:15am -10:45am

The goal of this session will be to discuss the current state of mobile health tools and mobile health apps and learn about new and upcoming wireless technologies to complement healthcare. At the end of this session, participants will have a better understanding of the challenges and possible uses of mHealth technologies in patient care and research. Participants will also be able to identify outcomes in health research and in shaping patient behavior.

Chairs:
Jennifer M. Kwan, MD, PhD, University of Illinois at Chicago College of Medicine, American Physician Scientists Association
Satish R. Raj, MD, MSCI, Associate Professor, Cardiac Sciences, University of Calgary

Confirmed Speakers:
Evan D. Muse, MD, PhD, Clinical Scholar, Scripps Translational Science Institute/Scripps Clinical
Linda Ricci, Cardiac Diagnostics Devices Branch Chief, Division of Cardiovascular Devices, FDA/CDRH/ODE
**Ivana Schnur, MD, PhD, Co-Founder, Sense.ly Inc.**  
**David Levin, MD, Partner, amatihealth, and Former Chief Medical Information Officer, Cleveland Clinic Health System**  
**Tim Shi, MD, PhD, SAS, CTM, Founder and Executive Director, GlobalMD Network Corporation**

<table>
<thead>
<tr>
<th>The Leadership Takes the Stage: Interactive Training in the Responsible Conduct of Research</th>
<th>9:15am – 10:45am</th>
</tr>
</thead>
</table>

“The Leadership Takes the Stage” is an interactive methodology using the performing arts as an avenue to fulfill NIH requirements for face to face training in Responsible Conduct of Research (RCR) and to provide training for the research community in general. Faculty takes on acting a 15 to 20 minute semi-staged vignette showcasing cases illustrating responsible conduct of research scenarios. The live performance of this original script is followed by an interactive debrief moderated session.

**Chair:**  
**Lisa Guay Woodford, MD**, Hudson Professor of Pediatrics and Associate VP for Clinical and Translational Research, The George Washington University; Director, Center for Translational Science and Director, CTSI-CN, Children’s National Health System

**Speaker:**  
**Adriana Brigatti, JD, MPH, LLM, CIP**, Director of Research Regulatory Affairs, Children’s National Medical Center

<table>
<thead>
<tr>
<th>Accelerating Translation</th>
<th>9:15am – 10:45am</th>
</tr>
</thead>
</table>

The “Science of Translational” and the discipline of “Regulatory Science” are emerging research areas addressing the mechanisms of Translation with a goal of speeding the process. Biological markers of normal function and disease states have produced tools whereby translation from laboratory bench to therapeutic armamentarium can be accelerated. Pioneering experts in the tools and the strategy will point the way. Selected meeting abstracts will be presented and discussed as examples of real and potential Accelerated Translation.

**Chairs:**  
**Anthony Windebank, MD**, Professor of Neurology, Program Director for Center for Clinical and Translational Science Predoctoral Programs, Director for Discovery for the Center for Regenerative Medicine, Mayo Clinic College of Medicine  
**Roy Weiner, MD**, Associate Dean for Clinical Research and Training; Associate Director of Clinical Research for Tulane Cancer Center; Professor of Medicine, Pediatrics, and Epidemiology; Edward G. Schlieder Educational Foundation Chair in Medical Oncology, Tulane University

**Confirmed Speakers:**

“**Personalized Immunotherapy for Advance Non-Small Cell Lung Cancer**”  
**Roy Herbst, MD, PhD**, Ensign Professor of Medicine, Professor of Pharmacology, Chief of Medical Oncology, Director, Thoracic Oncology Research Program, Associate Director for Translational Research, Yale Comprehensive Cancer Center, Yale School of Medicine

“**New Approaches to Accelerating Translation**”  
**Sherine Gabriel, MD**, Professor of Epidemiology and Medicine; Dean, Mayo Medical School, Mayo Clinic

|---|---|

This session explores the development of a machine learning approach to classifying research in peer-reviewed publications as part of tracking the movement of discoveries through the translational stages to implementation.
Participants will discuss the challenges in developing this approach and strategies to integrate this approach with other methods for tracking the movement.

Chair:
Joe D. Hunt, MPH, Associate Director, Tracking and Evaluation Program, Indiana Clinical and Translational Science Institute, Indiana University School of Medicine

Confirmed Speakers:
Alisa Surkis, PhD, MLS, Translational Science Librarian, NYU Health Sciences Library
Janice A. Hogle, PhD, Associate Director, Tracking and Evaluation, Institute for Clinical and Translational Research, University of Wisconsin, Madison
Deborah DiazGranados, PhD, Assistant Professor, Virginia Commonwealth School of Medicine

The Role of Evaluation in Translational Science Organizations 11:00am – 12:30pm

This panel examines the role evaluation plays or can play in organizations that are pursuing the changes necessary to advance clinical and translational science. Panel participants will provide insights on evaluation from 3 different perspectives: translation science program leaders, evaluators, and funders. Each participant will share their perspective on how evaluation processes and results can contribute to accountability, transparency, informed decision making, communication about outcomes and, ultimately, the value of the substantial investment in clinical and translational science.

Chair:
Julie Rainwater, PhD, Evaluation Director, Schools of Health, University of California Davis

Confirmed Speakers:
“The NCATS Clinical and Translational Science Awards Program and Evaluation”
Meryl Sufian, PhD, Program Officer, Division of Clinical Innovation, National Center for Advancing Translational Sciences (NCATS)/ National Institutes of Health (NIH)

“Domain Task Force Presentation: Methods and Processes”
William Trochim , PhD, Professor, Cornell University, Weill Cornell Clinical Translational Science Center

“Domain Task Force: Community Engagement”
Sergio Aguilar-Gaxiola, MD, PhD, Professor, UC Davis Health System, Director, UC Davis Center for Reducing Health Disparities

“Domain Task Force: Workforce Development”
Morris Weinberger, PhD, Vergil N. Slee Distinguished Professor of Healthcare Quality Management Department of Health Policy and Management Gillings School of Global Public Health University of North Carolina at Chapel Hill Senior Research Career Scientist, Durham VAMC Center for Health Services Research

“Domain Task Force Life Span”
Thomas Shanley, MD, Professor, University of Michigan

“Domain Task Force: Informatics”
Mitchel Krieger, MD, Associate Chief Information Officer, Cleveland Clinic

Translational Science Career Opportunities 11:00am – 12:30pm
Translational science occurs in many environments. The purpose of this session is to broaden the horizon and appreciate that the enablement of science occurs in government entities such as the FDA and the NIH, pharma and biotech industries and academia. This session will be a frank discussion that is focused on highlighting paths to career opportunities in for profit and not for profit sectors.

Chair:
Emma A. Meagher, MD, Senior Associate Dean, University of Pennsylvania

Confirmed Speakers:
Francisco Leon, MD, PhD, CEO and Chief Medical Officer, Celimmune LLC
Marcela Maus, MD, PhD, Assistant Professor of Medicine, University of Pennsylvania

“Thinking Inside the Black Box: Career Opportunities at the FDA”
Christopher Leptak, MD, PhD, Biomarker and Companion Diagnostic Lead, Office of New Drugs (OND, CDER, FDA)

The National Research Mentoring Network (NRMN):
Developing and Testing New Mentor Training Modules for Diverse Scholars  
11:00am – 12:30pm

Participants in this session will learn what resources and opportunities the newly funded National Research Mentoring Network (NRMN) has to offer to the biomedical research community. This will include a description of existing and newly developed research mentor training modules. Participants will engage in activities from two modules focused on work-life integration and cultural responsive mentoring and have the opportunity to provide feedback.

Chair:
Christine Sorkness, PharmD, Associate Director, Administrative Core, National Research Mentoring Network, Senior Associate Executive Director, Institute for Clinical and Translational Research; School of Medicine and Public Health; Distinguished Professor, School of Pharmacy, University of Wisconsin-Madison

Confirmed Speakers:
“The National Research Mentoring Network: An Overview”
Christine Sorkness, PharmD, Associate Director, Administrative Core, National Research Mentoring Network, Senior Associate Executive Director, Institute for Clinical and Translational Research; School of Medicine and Public Health; Distinguished Professor, School of Pharmacy, University of Wisconsin-Madison

“Mentor Training to Promoting Work-Life Integration”
Dennis Durbin, MD, MSCE, Professor, Pediatrics, Children’s Hospital of Philadelphia

“Mentor Training to Promote Culturally Responsive Mentoring”
Sandra Quinn, PhD, MEd, Professor, Family Science and Associate Dean for Academic Affairs and Senior Associate Director, Maryland Center for Health Equity, University of Maryland, College Park

Applications in Biomarker Research in Translational Science  
11:00am – 12:30pm

Biomarkers are indicators, frequently genes, proteins, or metabolites, of a particular disease state. They can be helpful for diagnosing diseases, investigating disease progression and the response to therapy, and are often used as targets for the development of new drugs. This session will cover several techniques that can be used to identify biomarkers from omics data as well as a specific application of how genomics biomarkers can be used to improve the power of clinical trials.

Chair:
Leah J. Welty, PhD, Associate Professor, Department of Preventative Medicine, Northwestern University Feinberg School of Medicine

**Confirmed Speakers:**

"Machine Learning Algorithms Used for the Identification of Potential Biomarkers"

Heidi M. Spratt, PhD, Associate Professor, Department of Preventive Medicine and Community Health, The University of Texas Medical Branch

"Can We Use Genomics and Adaptive Analysis to Make Clinical Trials Cheaper?"

Jeffrey T. Leek, PhD, Associate Professor, Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health

<table>
<thead>
<tr>
<th>Accelerated Clinical Trial Agreement: Streamlining the Contracting Process</th>
<th>11:00am – 12:30pm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commencing in August 2012, the Master Contracts Working Group consisted of 25 CTSA institutions collaborated with industry and the University Industry Demonstration Partnership to develop a standardized clinical trial agreement - a single agreement to be used (voluntarily) by each participating institution and sponsor, to reduce contract negotiations for industry sponsored multi-site studies specifically for Phase 2b and Phase 3 Clinical Trials. The ACTA has been finalized with 61 Institutions agreeing that the ACTA terms would be acceptable to their institution. The agreement is now being piloted with 5 Industry Sponsoring to gauge feasibility, utility and satisfaction metrics.</td>
<td></td>
</tr>
</tbody>
</table>

**Chair:**

Virginia Bruce, BS, Director, Legal Contract Administration, Mayo Foundation

**Confirmed Speakers:**

Libby Salberg, JD, Director, Office of Contract Management, Vanderbilt University

Virginia Bruce, BS, Director, Legal Contract Administration, Mayo Foundation

Terri Edwards, RN, RAC, Associate Director, Research Support Services, Vanderbilt University

<table>
<thead>
<tr>
<th>Closing Plenary Session</th>
<th>12:45pm – 1:45pm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funders increasingly seek predictors of “impact” as budgets tighten and near-term reward is sought at the expense of basic research. True accomplishment - scientific discoveries that actually impact on treatment and outcomes – often coincide with a cluster of surrogates of success but predicting winners, particularly amongst early stage investigators is an inexact art form. Some thoughts will be shared as to how best to approach this challenge.</td>
<td></td>
</tr>
</tbody>
</table>

**Confirmed Speaker:**

Garret FitzGerald, MD, FRS, Professor of Medicine and Pharmacology; McNeil Professor in Translational Medicine and Therapeutics; Chair, Department of Pharmacology; Director, Institute for Translational Medicine & Therapeutics. Perelman School of Medicine, University of Pennsylvania