Triangle Biotech Research Symposium IV:

Advancing Human Health through Technology Convergence

October 29, 2015 • North Carolina Biotechnology Center, Research Triangle Park

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8:00	Registration/Coffee +
9:00	Welcome- **Wanona Satcher**, CEO & Founder, iDrive Change
9:10	Keynote- **Paul Mugge**: Traversing the Valley of Death Professor of Innovation Executive Director Center for Innovation Management Studies (CIMS) North Carolina State University
10:00	**Converging Technologies: In Silico Approaches to Predicting Drug Induced Liver Injury** **Paul B. Watkins, M.D.** Professor of Medicine, Pharmacy, and Public Health University of North Carolina – Chapel Hill Director, Hamner – UNC Institute for Drug Safety Sciences
10:20	**Technology Convergence to Develop Tissue on Chip Models** **Frances Ligler, D. Phil., D. Sc.** Lampe Distinguished Professor of Biomedical Engineering UNC - Chapel Hill & NC State University
10:40	Break
11:00	**Panel: The CRISPR Revolution** **The Science, Current Applications, FDA Pathways** **MaryBeth Panagos**, Moderator Director, Business Development Kymanox **Rodolphe Barrangou Ph.D.,** Chair Associate Professor Department of Food, Bioprocessing and Nutrition Sciences North Carolina State University **Bryan R. Cullen, Ph.D.** James B. Duke Professor of Molecular Genetics & Microbiology Director, Duke Center for Virology Duke University Medical Center Durham, North Carolina **Charles A. Gersbach, Ph.D.** Assistant Professor Department of Biomedical Engineering Duke University
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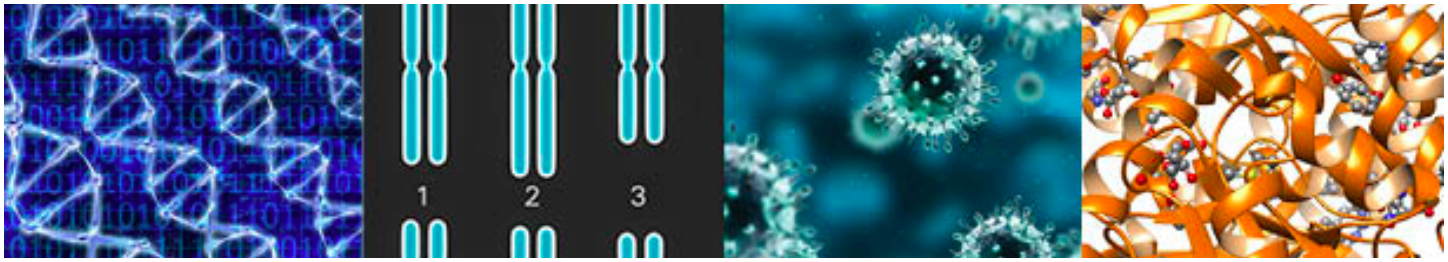

12:00	**Improving Tumor Characterization** **Dr. Hawazin Faruki, DrPH** Vice President for Clinical Development GeneCentric
12:20	Lunch
1:30	**Transforming Tobacco** **Todd Talarico, Ph.D.** Vice President of Process Development and Clinical Manufacturing Medicago
2:10	**Virtual Petting Zoo**- a Quick Walk Through Key Enabling Technologies
2:30	**Break**
2:50	**Faster No's, Accelerated Yes's** **Gabi Hanna, M.D.** Executive Director, Duke Preclinical Translational Research Unit Associate Director. Duke Cancer Institute, Surgical Facility Chairman of NC Society of Physician Entrepreneur Vice President, American Remote Health.
3:00	**Panel: The Funders' Role in Nurturing Convergence** **Moderator: Deborah Dougherty, Ph.D.** Professor, Management & Global Business Department Rutgers University **Christy Shaffer, Ph.D.** General Partner Hatteras Venture Partners Mary Musacchia, PLLC Chair, Board of Directors First Flight Venture Center, Inc. **Jay P. Madan** President and Founder Innovate Biopharmaceuticals, Inc.
4:00	**Adoption of Technologically Advanced Methods and Public Health Policies** **Rosalina Bray, MS, CAEP** Director of Research Project Teams National Society of Black Engineers Public Policy SIG
4:20	Closing Remarks, Adjourn

Speakers Bios:

Keynote: **Paul C. Mugge,** Professor of Innovation,
Executive Director, Center for Innovation Management Studies (CIMS)
North Carolina State University

At IBM, Mr. Mugge was part of a team that developed the industry's first capability to simulate, test and manufacture VLSI (Very Large Scale Integration) circuit, and also served on the design team that pioneered IBM's first self-diagnosing, self-healing computing system. Additionally, he led the IBM task force that conceived the beloved IBM ThinkPad. Mr. Mugge received the IBM Innovation Achievement Award for the overall design and program management of the company's first rack-mounted, "supermini-mainframe," the IBM 9370 and was also awarded IBM Chairman's Award for leading re-engineering of its hardware and software businesses.

Rodolphe Barrangou, Ph.D.
Associate Professor, Department of Food, Bioprocessing and Nutrition Sciences, North Carolina State University

For more than 10 years, Dr. Barrangou has focused on CRISPR-Cas systems, and their use for bacterial genotyping, building prokaryotic immunity, and Cas9-mediated genome editing in industrial bacteria. He is a co-founder of Intellia Therapeutics.

Dr. Barrangou earned a BS in Biological Sciences, a MS in Biological Engineering, a MS in Food Science from NC State University, a PhD in Genomics from NC State University and a MBA from the University of Wisconsin-Madison. After 9 years in R&D and M&A at Danisco and DuPont, he joined the Faculty at NC State University in 2013.

Rosalina Bray, MS, CAEP
Director of Research Project Teams, National Society of Black Engineers Public Policy SIG

Bryan R. Cullen, Ph.D.
James B. Duke Professor of Molecular Genetics & Microbiology and Director, Duke Center for Virology, Duke University Medical Center

Bryan R. Cullen obtained a B.Sc. in Biochemistry from Warwick University in the UK and a M.Sc. in Virology from the University of Birmingham before moving to the USA, where he obtained a Ph.D. in Microbiology from Rutgers University. In 1987, he was recruited to Duke University Medical Center as a Howard Hughes Medical Institute Investigator. He currently holds a James B. Duke Professorship in the Department of Molecular Genetics and Microbiology and serves as Director of the Center for Virology at Duke. Dr. Cullen's current research interests include the biogenesis and function of microRNAs, in particular viral microRNAs as well as the use of CRISPR/Cas for the specific editing of viral DNA genomes. Dr. Cullen has published over 300 research papers and is on the editorial board of 11 prominent journals.

Dr. Hawazin Faruki, Ph.D., Vice President for Clinical Development, GeneCentric

Dr. Faruki has over 15 years experience in transitioning novel molecular diagnostic testing from the research setting to the clinic. She served as Vice President of Clinical Development, and previously as Vice President of Operations, at Laboratory Corporation of America's Center for Molecular Biology and Pathology guiding the successful introduction of numerous molecular diagnostic assays, including infectious disease, oncology, and genomic applications.

Dr. Faruki has authored several peer-reviewed publications on factors impacting adoption of new molecular and genomic diagnostics and has extensive experience in clinical study design, securing CPT coding and fair reimbursement, and educating physicians regarding new test applications. Since her departure from LabCorp, she has managed a successful consulting business, Clinical Diagnostic Strategies, LLC, focused on assisting biotech companies with the introduction of personalized medicine diagnostics. Dr. Faruki received her doctorate in Public Health Laboratory Practice from the University of North Carolina School of Public Health and completed a fellowship in clinical microbiology at Washington University in St. Louis, MO.

Charles A. Gersbach. Ph.D.

Associate Professor of Biomedical Engineering and Orthopaedic Surgery and Director, Center for Biomolecular and Tissue Engineering
Investigator, Center for Genomic and Computational Biology, Duke University
Dr. Charles A. Gersbach is an Associate Professor at Duke University in the Departments of Biomedical Engineering and Orthopaedic Surgery, an Investigator in the Duke Center for Genomic and Computational Biology, and Director of the Duke Center for Biomolecular and Tissue Engineering. He received his PhD from the Georgia Institute of Technology and completed postdoctoral training at The Scripps Research Institute. His research interests are in genome and epigenome editing, gene therapy, regenerative medicine, biomolecular and cellular engineering, synthetic biology, optogenetics, and genomics. Dr. Gersbach's laboratory at Duke University is focused on applying molecular and cellular engineering to develop new methods to genetically modify genome sequences and cellular gene networks in a precise and targeted manner. Dr. Gersbach's work has been recognized through awards including the NIH Director's New Innovator Award, the NSF CAREER Award, and the Outstanding New Investigator Award from the American Society of Gene and Cell Therapy.

Joanne Gere, Executive Director, BioPharma Research Council

Ms. Gere took on the role at the BRC in 2013, working closely with the Scientific Advisory Board, the Young Investigators Group, the Business Roundtable and the Innovation Research Roundtable. Since then the organization's constituency has grown more than three-fold to 9,500 scientists. This lively association reaches out across all of the many silos of biomedical research, building a strong platform for stimulating collaborations and partnerships. Throughout the year, the BRC presents webinars, conferences, and symposia to help connect professionals who would not likely find each other.

She is a serial entrepreneur and investor with experience working with publishing, banking for the unbanked, renewable energy, and medical devices. While president of the Association for Women in Science, NJ Chapter, she expanded its scholarship program, and worked with regional chapters and the Chemical Heritage Foundation to present the AWIS@40 conference.

Gabi Hanna, M.D.
Executive Director, Duke Preclinical Translational Research Unit and Associate Director. Duke Cancer Institute, Surgical Facility
Chairman of NC Society of Physician Entrepreneurs and Vice President, American Remote Health

The Duke Preclinical Translational Research Unit is a developing CCSG Shared Resource which provides Duke or external investigators the opportunity to carry out critical in vivo experiments in a semi-independent laboratory, with input and oversight from experts in cancer biology, statistics, medical device, and animal experimentation, while having available all of the resources and expertise present at Duke. Our goal is to generate high quality, documented data, focusing on traceability, scientific rigor, documentation, and timeliness.

Frances S. Ligler, D.Phil., D.Sc.
Lampe Distinguished Professor, Department of Biomedical Engineering, UNC-Chapel Hill and NC State University

Frances S. Ligler is the Lampe Distinguished Professor in the Department of Biomedical Engineering at NC State and UNC Chapel Hill and a member and Councillor of the National Academy of Engineering. She earned a B.S. from Furman University and both a D.Phil. and a D.Sc. from Oxford University. She has 400 full-length publications and patents, which have led to eleven commercial biosensor products and over 13,000 citations. Elected a Fellow of SPIE in 2000, of AIMBE in 2011, and of AAAS in 2013, she was awarded the Presidential Rank of Distinguished Senior Professional by President Bush (2003) and the Presidential Rank of Meritorious Senior Professional by President Obama (2012). In 2014, she was awarded an honorary doctorate from the Agricultural University of Athens, Greece.

Jay P. Madan, President and Founder , Innovate Biopharmaceuticals, Inc.

Mr. Madan has 25+ years in biotech, life sciences, and IT as a leader in project development, driving emerging market technology development, tech transfer, M&A, and cross-licensing. Mr. Madan has founded more than a dozen companies, including 2 biotech startups. His experience in working with multiple teams at Reliance Life Sciences, Millipore, Baxter, Dade Behring, and Goodwin has allowed him to develop a very high quality global network of industry professionals in various aspects of healthcare. Mr. Madan is president and founder of Innovate Biopharmaceuticals, NexGen Biosciences, and iBiotech, and manages Healthcare Sherpa and iCool Technologies. He was the VP of Business Development at Reliance Biopharmaceuticals Pvt. Ltd. part of Reliance Industries Ltd., India's largest conglomerate. Mr. Madan holds a Bachelor of Chemical Engineering from University of Mumbai and an M.S. in Chemical Engineering from Washington State University.

Mary U. Musacchia, JD, Chair, Board of Directors, First Flight Venture Center, Inc.

Mary U. Musacchia is the Board Chair and an Executive in Residence at First Flight Venture Center, the RTP's oldest incubator, as well as a practicing attorney. For the last decade Mary has focused on emerging growth companies providing advice on negotiation strategies, business operations and relationships with strategic partners. She is a past Board Chair of the Council for Entrepreneurial Development.

Mary has years of executive level experience with large multinationals including Sr. V.P. at Affiliated Computer Systems and 17 years with SAS Institute where she served as Director of Global Government Affairs and General Counsel. She is a frequent speaker on board governance and is a member of the National Association of Corporate Directors and Women Corporate Directors. In 2013 she was recognized by the NC Women's Forum for her years of service on public boards and commissions and in 2001 received the Triangle Business Journal's 'Women in Business Award'.

Christy Shaffer, Ph.D., General Partner, Hatteras Venture Partners

Seasoned entrepreneur and biotech executive, Christy Shaffer, Ph.D. has over 25 years of experience in the life science industry. Following her career as a clinical scientist, international project leader and Associate Director of Pulmonary and Critical Care Medicine at Burroughs Wellcome Co., she joined Inspire Pharmaceuticals in 1995 as the first, full-time employee. She was responsible for raising over $300m for the company, including taking the company public in 2000. As President and CEO, Christy grew the company from 20 scientists to nearly 250 employees with revenues of over $100 million. Under her leadership, Inspire was named as "Best Place to Work for Scientists" by the Scientist magazine, and "Best Place to Work in North Carolina." Christy retired from Inspire in 2010. Inspire was acquired by Merck in 2011.

Christy serves as a board member of five Hatteras portfolio companies and chairs three of them: G1 Therapeutics, Spyryx, Clearside (Chair), KinoDyn (Chair), and GrayBug (Executive Chair). Christy is a receptor pharmacologist by training, earning her Ph.D. in Pharmacology from the University of Tennessee Health Science Center, Memphis TN in 1985. She received her post-doctoral training at The Chicago Medical School and the University of North Carolina at Chapel Hill.

Todd Talarico, Ph.D. Vice President of Process Development and Clinical Manufacturing, Medicago, USA, Inc.

Todd was responsible for Medicago's completion of an aggressive design-build, government funded project resulting in rapid construction and deployment of a NC facility designed to produce more than 10 million pandemic influenza vaccine doses in 30 days, produced in and purified from tobacco plants. Todd just completed leading a second government-funded project to produce anti-Ebola monoclonal antibodies in the same plants. He has also been involved in the Research Triangle Park operations for development of biopharmaceuticals for Apex Bioscience and AlphaVax in the past. Todd received a BS in Chemical Engineering from Penn State and a Ph.D. in Microbiology from NC State.

Dr. Paul Watkins
Director of the Hamner-University of North Carolina Institute for Drug Safety Sciences.
Professor of Medicine, Pharmacy, and Public Health at the University of North Carolina, Chapel Hill.

Dr. Watkins is a trained clinical hepatologist and also an accomplished basic and translational investigator in the fields of drug metabolism and hepatotoxicity. He serves as the chair of both the Steering and Genetics Committees for the U.S. Drug-Induced Liver Injury Network (DILIN) (U01DK065201). He also directs the DILIsim Initiative, which is a public-private partnership involving scientists from 13 major pharmaceutical companies and the FDA. Dr. Watkins is one of the most frequently cited authors in the field of pharmacology according to www.ISIhighlycited.com. He is the recipient of numerous honors and awards including the 2009 Therapeutic Frontiers Award from the American College of Clinical Pharmacy, the 2013 Agilent Therapeutic Frontiers Award, and the 2015 Rawls-Palmer Award for Progress in Medicine from the American Society for Clinical Pharmacology and Therapeutics.

Technology Convergence to Predict Liver Safety of New Drug Candidates.

Establishing liver safety remains a major challenge in drug development. The DILIsim Initiative is a public-private partnership that is developing sequential versions of software (currently DILIsym® v 4.0), that uses data obtained without animals to predict the liver safety of new drug candidates. This Hamner-based initiative involves scientists from 13 major pharmaceutical companies, UNC, Duke, and the FDA. In addition to financial support, participating companies provide unpublished data and perform in kind research to fill gaps in knowledge. The software produced by the initiative has already been used in regulatory submissions in the US and Europe. An RTP based company, DILIsym Services, Inc, has been recently established for proprietary projects.