



National Heart, Lung,
and Blood Institute

NHLBI Regional Innovation Conference - Midwest

March 4, 2015 • OSU Wexner Medical Center
Columbus, OH



PARTNERS



THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER
The Dorothy M. Davis Heart & Lung Research Institute



Agenda

- 9:00am Welcome Remarks and
NHLBI Overview and
Resources
- 9:45am Company Presentations A
CleveMed Devices
Imbio
Antegrin
- 10:30am Refreshments and
Partnering
- 11:00am Reimbursement Presentation
- 11:30am Company Presentations B
3PrimeDX
EXCMR
Nanova
Great Lakes Pharmaceuticals
- 12:30pm Lunch and Partnering
- 1:30pm NCAI Presentation
- 2:00pm Company Presentations C
Viaderm
MC3
Integrated Sensing Systems
- 2:45pm Partnering Break
- 3:15pm Investor Perspective Panel
- 4:30pm Closing Remarks
- 4:45pm Reception

Speakers



Kurt Marek, PhD

Dr. Marek is the Deputy Director of the Office of Translational Alliances and Coordination (OTAC) at the National Heart, Lung, and Blood Institute (NHLBI). OTAC is charged with developing trans-NHLBI programs to foster the translation of early stage discoveries into commercial products. The Office coordinates the NIH Centers of Accelerated Innovations and the Institute's small business program. Dr. Marek oversees the Institute's efforts to support small businesses performing research and development on innovative biomedical products and to facilitate partnerships between small businesses, investors and strategic partners.



Chris Sasiela, PhD, RAC

Dr. Sasiela is the Regulatory Specialist in the NHLBI Office of Translational Alliances and Coordination. She provides consultative advice and develops regulatory affairs educational content for NHLBI small businesses, clinical investigators, and program staff. She also facilitates communication between NHLBI-funded investigators and the FDA.



Marilyn Denegre-Rumbin, MBA

Marilyn has over 25 years' experience in the healthcare arena, from hospital administration, practice management, healthcare contracting and network development. She specializes in healthcare areas focused on reimbursement and product commercialization services, identifying opportunities to leverage the lifecycle of medical technologies.



Mark Low

Mr. Low is Managing Director of the NIH Center for Accelerated Innovations (NCAI) at Cleveland Clinic and the Global Cardiovascular Innovation Center (GCIC). He comes to these roles with a track record of building successful programs to introduce new biomedical products and modalities to new markets. He has managed all facets of product and market development spanning diagnostic and interventional cardiology, diagnostic and interventional pulmonology, interventional radiology, stroke treatment, image-guided surgery, drug delivery and oncology. Prior to concentrating his focus on start-up ventures and early stage market development, Mark held trailblazing positions in marketing and business development for Hewlett-Packard's Medical Products Group.

Panelists



Stephen Flaim, PhD (Moderator)

Dr. Flaim is Special Advisor in the NHLBI Office of Translational Alliances and Coordination, Chairman Emeritus of Tech Coast Angels, and Director of the Angel Capital Association. He is Founder and President of Flaim Partners Consulting and a board member of Pivotal Biosciences Inc. and AnaBios Corp. Dr. Flaim is Chairman of the Board for Leading Biosciences Inc. and technology and business adviser to the William J. von Liebig Center for Entrepreneurism and Technology Advancement at UC San Diego.



Mark Boden, PhD

Dr. Boden is a senior fellow in the Corporate Research Division at Boston Scientific. He has been at the company for ten years, working on interventional cardiology, peripheral vascular, urology, women's health, and endoscopy projects. Dr. Boden has a doctorate from UMass Lowell in Polymer Chemistry and Plastics Engineering and specializes in biomaterials, drug/device combination products and early stage research into disease states.



John Huston, MBA

Mr. Huston is manager at Ohio Tech Angels. After his 30-year banking career, he formed USPrivateCompanies, LLC which has provided capital to 50+ Ohio entrepreneurs. He is also responsible for launching the first Ohio TechAngel Fund (OTAF), which then became the founding member of the Angel Capital Association (ACA) and is now one of the world's largest angel groups. Mr. Huston is also internationally known as the past Chairman of both the ACA and the Angel Resource Institute (ARI).



Peter Kleinhenz, CPA, MBA

Mr. Kleinhenz is Managing Director of CID Capital, Inc., Venture Capital where he leads the firm's investments in life sciences companies. He also serves as Venture Partner at Fletcher Spaght Ventures, LP (FSV). Mr. Kleinhenz has been actively involved in technology-based businesses as an entrepreneur, consultant, and investor for over 25 years and has provided leadership for new venture formation in the life sciences sector for over 20 years.



Beverly Lyman, PhD

Dr. Lyman is a patent attorney and a partner in the firm's Intellectual Property, Corporate and Life Sciences practice groups. A former faculty member at the medical campus of the University of Tennessee, she now focuses on intellectual property transactions, evaluation, enforcement, and prosecution in chemical, medical, and life science areas, with a particular interest in university monetization of its intellectual assets.



Erik Woods, PhD

Dr. Woods co-founded General BioTechnology in 1997, an R&D company devoted to advancing cell culture and cryopreservation to facilitate mainstream clinical use of cellular therapies. He was the first full-time employee of the company and in 2000 became President and CEO, ultimately leading it through successful acquisition by COOK Medical in 2012. Dr. Woods currently serves as Senior Vice President and Lead Scientist for COOK Regentec, a COOK Group company formed in January of 2015 to continue commercialization of products conceived at General BioTechnology and find/develop new, innovative technologies for regenerative medicine.



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Showcase Companies

Devices



CleveMed develops portable monitoring and web-based technologies for sleep disorders evaluation in the home. CleveMed has a growing range of products including SleepView®, the smallest and lightest monitor in the marketplace, and SleepViewSM Web-portal, powerful web-based software that connects healthcare providers with a network of sleep specialists across the country. **Poster 4** **9:45AM Presentation**



Imbio is a medical imaging company commercializing unique imaging biomarkers. Imbio's mission is to transition imaging biomarkers pioneered in the academic research world to routine clinical use. Imbio refines these biomarkers beyond the initial prove-out stage and works under accredited design controls to create commercial medical software.

Poster 7 **10:00AM Presentation**



ViaDerm is developing a second generation percutaneous access device. The ViaDerm 2™ will proactively reduce infection at the site of skin penetration of a catheter or drive line required for prolonged delivery of life-sustaining therapies. The ViaDerm 2 device accelerates tissue attachment by combining a proprietary microtextured surface technology with a unique wound vacuum system. **Poster 11** **2:00PM Presentation**



Nanova is an early-stage biotechnology company developing dual-functional and non-drug based coronary stents to prevent both restenosis of coronary arteries and late in-stent thrombosis for treatment of coronary heart disease. **Poster 10** **12:00PM Presentation**



Great Lakes Pharmaceuticals is a clinical stage company developing an anti-microbial catheter lock solution (B-Lock solution), for the prevention of life-threatening infections caused by central venous catheters. B-Lock is a safe and highly effective broad spectrum antimicrobial catheter lock solution that sanitizes the inside of the catheters to prevent deadly blood stream infections, save lives and reduce healthcare costs. **Poster 6** **12:15PM Presentation**



EXCMR develops and markets innovative products that enhance cardiovascular magnetic resonance imaging (MRI). The Company's patent pending MRI-compatible treadmill forms the basis for the first ever "next to magnet" exercise stress system enabling peak stress MR imaging of dynamic heart and vascular structures. **Poster 5** **11:45AM Presentation**



MC3 develops and commercializes solutions for complex cardiopulmonary disease etiologies with the goal of advancing early-stage medical device extracorporeal support technologies. MC3 is developing a simplified extracorporeal blood pumping system that will be marketed as an ER based E-CPR system for refractory cardiac arrest patients. **Poster 8** **2:15PM Presentation**



Affinity Therapeutics is developing a drug delivery platform capable of sustained, customizable delivery of therapeutic agents. Affinity's delivery platform utilizes molecular interactions with a therapeutic agent to extend the delivery profile beyond what is seen from current delivery technologies. The first two areas of interest are preventing device infection and improving vascular access outcomes for hemodialysis patients. **Poster 1**



Arrhythmotech is developing a cardio monitoring device called the neuECG that allows for the non-invasive recording and signal processing of sympathetic nerve activity (SNA) and electrocardiogram (ECG). The simultaneous detection of both SNA and ECG offers a low-cost advantage in risk stratifying patients who are at risk of cardiovascular diseases like Sudden Cardiac Death (SCD). **Poster 2**

Showcase Companies

Devices (cont'd)



BEzenwa Biomedical Engineering develops medical device innovations for preventive, restorative, assistive and rehabilitative systems. The “muscle fiber excitation system” (MFES) provides wearable, concealed technology to prevent blood clots at any anatomic region.

Poster 3



MSP Corporation sells products and services to aerosol researchers, and the pharmaceutical industry and semiconductor industry. The company is also pursuing development of novel drug delivery devices. Besides providing innovative instrumentation to aerosol scientists, MSP has developed devices and materials that are routinely used in life science, pharmaceutical, and semiconductor industries. **Poster 9**

Diagnostics



3PrimeDx develops cardiac diagnostic and theranostic tests. Its lead product is a novel, first-in-class, blood test (PulsePredic™) designed to predict risk of Sudden Cardiac Death (SCD) in individuals with heart failure. PulsePredic™ measures mRNA splice variants of the SCN5A sodium-channel gene by polymerase chain reaction (PCR). **Poster 12 11:30AM Presentation**



Integrated Sensing System designs, develops, and manufactures wireless, batteryless, miniature, implantable, diagnostic, pressure sensors for long-term home monitoring of chronic diseases. The lead product is a novel cardiac implantable pressure monitoring system that provides remote cardiac pressure monitoring to enable tailored treatments for disease management. **Poster 14 2:30PM Presentation**



Columbus NanoWorks is developing fluorescent (nitrogen-vacancy center) diamonds for in vitro and in vivo biomedical applications. They are being developed as labeling reagents for cell and molecular biology applications as well as optical imaging agents for in vivo applications. **Poster 13**



Magnetic Resonance Innovations provides quantitative diagnostic data analysis tools for neurovascular and cardiovascular diseases, such as traumatic brain injury, stroke, vascular dementia and Parkinson's disease. The state-of-the-art image processing software SPIN (Signal Processing In Nuclear magnetic resonance) consists of user-friendly, fully automated diagnostic and quantitative analysis modules (available in an on-demand cloud environment). **Poster 15**

Therapeutics



Antegrin Therapeutics develops therapies for fibrotic diseases. Antegrin is initially focused on an inhaled therapy for idiopathic pulmonary fibrosis, a progressive, life-threatening condition. Antegrin's small-molecule compounds have the unique ability to block the function of five specific integrins, members of a family of human proteins that are locally up-regulated at sites of fibrosis and that contribute to fibrotic pathology. **Poster 16 10:15AM Presentation**



Cell Biologics identifies candidate molecular probes for the therapy of vascular inflammatory diseases. Cell Biologics also specializes in custom primary human or mouse endothelial and epithelial cell isolation. It provides a broad range of high-quality human and animal primary cells including endothelial, epithelial, tumor and stem cells, along with optimized cell culture media and other culture related products. **Poster 17**



EVAS Therapeutics is a preclinical-stage biopharmaceutical company focused on developing novel therapeutic proteins for treatment of a wide range of ischemic cardiovascular diseases. EVAS' proprietary drugs comprise a series of patented recombinant proteins with Annexin V and Kunitz Inhibitor domains. **Poster 18**



Sovelis develops and commercializes high throughput, innovative assay platforms for detecting abnormal heart rhythm (arrhythmia) substrates in patients. A major public health concern is adverse cardiac events associated with non-cardiac drugs and ineffective drug therapy that is intended to prevent arrhythmia. **Poster 19**

Showcase Companies

Research Tools



BellBrook Labs develops proprietary detection reagents and microfluidic devices that accelerate the discovery of more effective therapies for cancer and other diseases. Transcreener® is a universal, high throughput biochemical assay platform for enzymes that catalyze post-translational modifications. The iuvo™ Microconduit Array Plates are microscale devices for automated high content analysis of physiologically relevant tissue models and phenotypic endpoints on existing HTS platforms. **Poster 20**

NCAI-CC Innovators

The NIH Centers for Accelerated Innovation (NCAI) program translates discoveries emerging from academic labs into novel diagnostic and therapeutic products. The NCAI in Ohio, which includes the Cleveland Clinic, Case Western Reserve University, The Ohio State University, University of Cincinnati, and Cincinnati Children's, is one of three NHLBI-funded Centers in the country. www.ncai.nhlbi.nih.gov



Nanofiber Solutions is developing a new class of implants for soft tissue and organ repair/regeneration, and three-dimensional cell culture products that advance research in cellular therapeutics and drug discovery. **Poster 21**



Oral THU-decitabine, a novel non-cytotoxic epigenetic therapeutic is a new combination drug treatment (dual-release oral decitabine) that could prevent the advancement of sickle cell disease and other diseases involving the oxygen carrier hemoglobin in red blood cells, as well as bone-marrow cancers. **Poster 22**

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 **National SBIR/STTR Conference**
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 **BIO International Conference**
June 15-18 Philadelphia, PA

The NHLBI Office of Translational Alliances and Coordination

The Office of Translational Alliances and Coordination (OTAC) helps to move basic discoveries from laboratory to market to improve health. OTAC does this by providing leadership for the NHLBI small business program and developing trans-NIH SBIR/STTR funding opportunities, supporting universities' efforts to create new technology development models, providing expert regulatory and commercialization advice to the NHLBI community, and developing strategic partnerships.

The National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) provides global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives.

The National Institutes of Health

The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services, is the nation's medical research agency—making important discoveries that improve health and save lives.