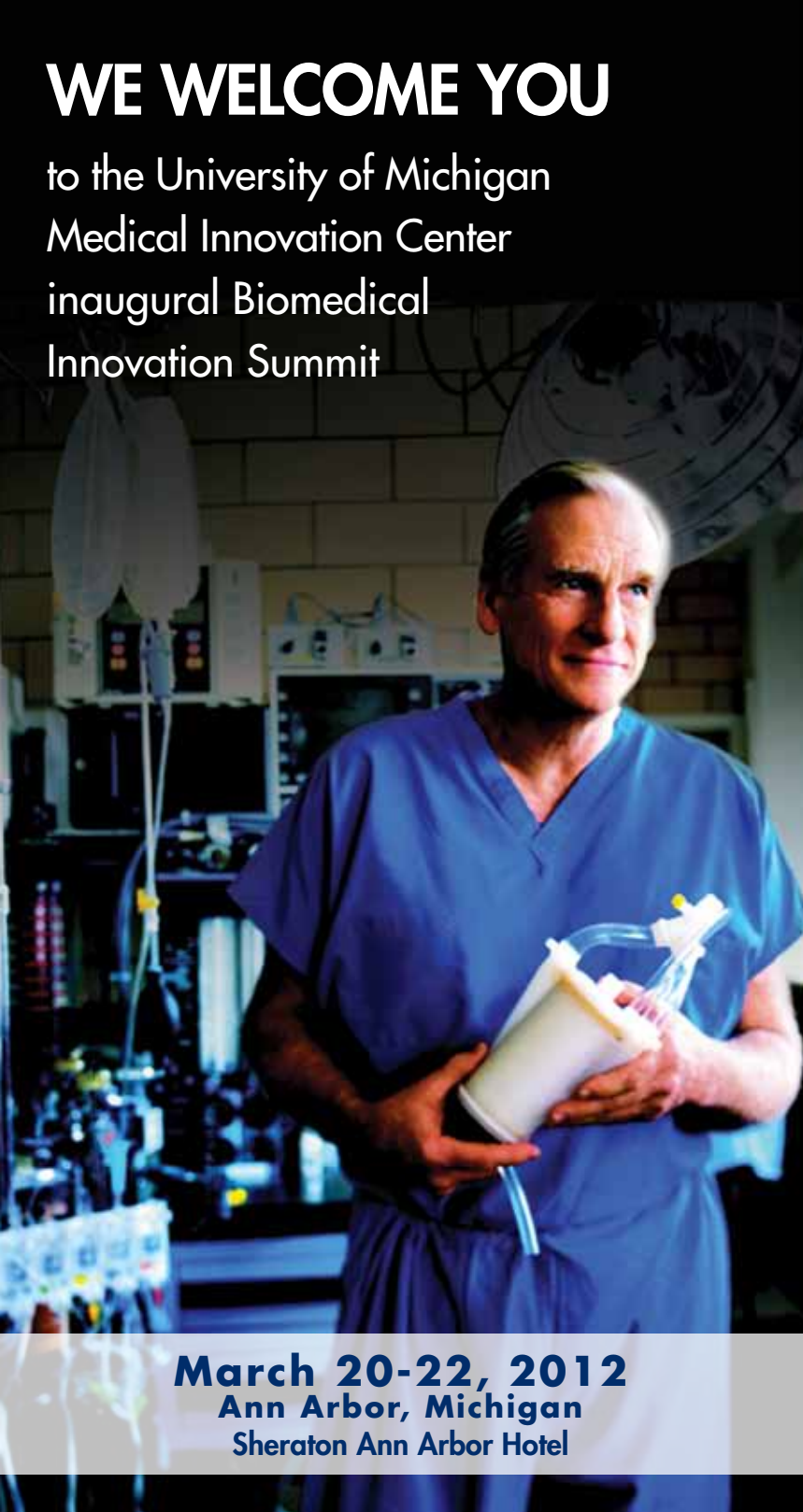
WE WELCOME YOU

to the University of Michigan
Medical Innovation Center
inaugural Biomedical
Innovation Summit



March 20-22, 2012
Ann Arbor, Michigan
Sheraton Ann Arbor Hotel

University of Michigan

Medical Innovation Center

By 2025, the global population will exceed eight billion people. Delivering life-saving biomedical innovations to all segments of the global population–particularly the under-served pediatric segment – poses one of the greatest challenges of our time.

Please join us on March 20-22, 2012 in Ann Arbor, Michigan for the University of Michigan Medical Innovation Center (MIC) inaugural Biomedical Innovation Summit. Global participants from industry, academia, and government will converge to witness pediatric product success stories, develop strategies for overcoming commercial barriers, and collaboratively design solutions for emerging pediatric clinical markets.

MEDICAL INNOVATION CENTER
UNIVERSITY OF MICHIGAN

University of Michigan Health System

University of Michigan C.S. Mott Children's Hospital

M-PED Pediatrics Device Consortium

Tuesday, March 20, 2012

Afternoon • Optional tours of new C.S.Mott Children's Hospital, University of Michigan Medical Innovation Center and other Ann Arbor research complex facilities
• Pediatric Innovation, Consortium, and Innovator Meetings

Evening • Welcome reception for all attendees (cocktails & appetizers)

Wednesday, March 21, 2012

	SESSION TYPE	TITLE	SUMMARY	CURRENT SPEAKERS
8:30 AM	Welcome			
9:30 AM	Keynote	Innovation Process - Promises & Problems in Pediatric Device Development	Problems - Why does industry have problems with pediatrics? Experiences from innovator end	Dan Strauch, GE Healthcare Rick Ohye, MD, U-MICH Martin Bocks, MD, U-MICH
10:30 AM	Observation Panel	Observing Pediatric Procedures & Treatments - Case Studies	Demonstration of pediatric procedures utilizing adult tools	Larry Schmitt, PhD Jim Geiger, MD-UM Andre A. Muelenaer, Jr.,MD, MS, PMDI Dan Teitelbaum, MD-UM
12:00 Noon	Lunch	ECMO pioneer & pediatric innovator	An evolving success story	Bob Bartlett, MD
1:00 PM	Networking	Exhibit Hall open		
1:30 PM	Speaker	Inspiring Out-of-the-Ordinary Design for Pediatric Products	Overview of Product Design Approaches	Curt Bailey, President, Sundberg-Ferar, Inc
2:30 PM	Breakout	From Design to Proof of Concept - Medical Device/Diagnostic Panel	Design Principles/ Product Planning/ Proof of Concept	Anil Mankodi, Medtronic CRDM Brad Slaker, MBA, DesignWise Medical
2:30 PM	Breakout	From Design to Proof of Concept – Therapeutics Panel	Design Principles/ Product Planning/ Proof of Concept	Other Speakers TBA
4:30 PM	Networking	Exhibit Hall open		
6:00 PM	Dinner	Pediatric Innovator Awards	Look for nomination form	

Thursday, March 22, 2012

	SESSION TYPE	TITLE	SUMMARY	CURRENT SPEAKERS
8:45 AM	Plenary	Pediatric Product Development Accelerated by Global Partnerships	Design, engineering, and fundraising for pediatric products requires innovative partnerships, and innovative approaches	Scott Merz, PhD, President MC3
9:45 AM	Networking Break	Exhibit Hall open		
10:15 AM	Panel & Working Session 1	Navigating Manufacturing and Trials in a Global Context	Overview of manufacturer approaches to pediatric products, pediatric trial strategies, pediatric trial network updates.	P. Brian Smith, MD-Duke Andre Muelenaer, MD - Carilion Clinic & PMDI James Huttner, MD, VP, New Product Development, Bionix
11:40 AM	Networking Break	Exhibit Hall open		
12:00 Noon	Lunch			
1:00 PM	Networking Break	Exhibit Hall open		
1:30 PM	Mitigating Risks Panel	IP, Regulatory, & International Perspectives	Regulatory and reimbursement perspectives to mitigating risks for pediatric products	Susan Alpert PhD, MD Former Medtronic VP
2:30 PM	Panel & Working Session 2	Distribution, Financing, and Exit	Clinical adoption, licensing, acquisition, and fundraising for niche or pediatric markets is no small challenge	Working session facilitators
3:45 PM	Networking Break	Exhibit Hall open		
4:15 PM	Future Opportunities & Next Steps	Global Resources, Initiatives, & Partnering	Government, academia, CRO's, and the others partnering will create the future for pediatric biomedical innovations	
	Conclusion and the THE PATH forward			

Speaker Biographies

Dan Strauch, B.S.E. Corperate Keynote

Director of Marketing – Maternal Infant Care, GE Healthcare

GE Healthcare Dan Strauch has been involved in the development and marketing of products for the neonatal intensive care unit for the past seventeen years. Dan has traveled extensively through the United States, Europe, the Middle East and Asia to understand the varying needs of caregivers in these diverse settings. As the Director of Marketing for GE Healthcare's Maternal Infant Care business segment, Dan is responsible for the strategic direction of products for both the "developed" and "emerging" markets. Dan holds a BSE in Mechanical Engineering from Duke.

Richard G. Ohye, M.D. Academic Clinical Keynote

Associate Professor of Surgery, Director, Pediatric Cardiac Surgery
Director, Pediatric Cardiovascular Transplant Program Program
Director,Thoracic and Congential Cardiac Surgery Residencies

Dr. Ohye is a congenital heart surgeon and the Head of the Section of Pediatric Cardiovascular Surgery at the University of Michigan Congenital Heart Center, one of the two largest congenital heart programs in the United States. He has a particular interest in pediatric cardiac device development, clinical research, and the importance of evidence-based medicine. He is currently the study chair of a 15-cente prospective clinical trial through the Pediatric Heart Network, funded by the NHLBI. Dr. Ohye is also a member of the Pediatric Device Consortium and is on the NHLBI committee developing the clinical trials to test the next generation of ventricular assist devices and ECMO circuits. Dr. Ohye's major clinical interests are in complex congenital heart defect repair and pediatric heart transplantation.

Martin Bocks, M.D. Academic Clinical Keynote

Assistant Professor of Pediatrics and Internal Medicine

Dr. Bocks is an Assistant Professor of Pediatrics and Internal Medicine at the University of Michigan, and is one of the faculty members within the Division of Pediatric Cardiology and the Michigan Congenital Heart Center. His clinical interests include pediatric and adult interventional cardiac catheterization on patients with structural heart disease. Dr. Bocks' research interests include pediatric cardiac device development and animal model optimization for medical device testing. Working in collaboration with Integrated Sensing Systems, Inc., Dr. Bocks serves as the UM principal investigator on a project to develop an implantable wireless sensor to measure pressures within the hearts of infants and children with complex congenital heart disease. He is the site PI for an NIH SBIR grant that supports the final stages of device design and prototype development and testing. He also is a co-investigator within the Extracorporeal Life Support Research Laboratory at the University of Michigan.

Curt Bailey, D.S.E., M.D.A.

President, Sundberg-Ferar, Inc.

Curt's three favorite subjects in high school were Art, Auto Shop, and Debate. His guidance counselor thought he would be great at haggling over the price of his paintings in front of a gas station. Instead he chose a career in product development. Curt is the President of Sundberg-Ferar, a 77+ year old product development consulting firm that helps companies in a wide variety of industries including housewares, transportation, medical, recreational, and consumer electronics leverage the power of design to de-commoditize their products. Sundberg-Ferar employs market researchers, strategic planners, industrial designers, engineers and prototypers. Curt is named as primary inventor on dozens of U.S. patents and has spoken at numerous events on the process of designing products with an emotional appeal. Curt joined Sundberg-Ferar in 1983 and has been President since 1992.

Scott Merz, Ph.D.

President, Michigan Critical Care Consultants (MC3)

Scott Merz, Ph.D. co-founded MC3 in the early 90's, while he was completing his Ph.D. in Biomedical Engineering at the University of Michigan. MC3's mission is to identify promising early-stage medical device technologies and to complete design and product development, with the goal of working with investors and strategic partners for production and commercialization. MC3 has worked with inventors, universities and established medtech companies to develop a variety of devices and incubate businesses that have resulted in license deals and the formation of several venture-backed startups. MC3 has been involved with international collaborations, particularly in the field of respiratory support. MC3 has also worked on several devices for pediatrics, where they strive to create innovative, cost efficient solutions. One example is the Pediatric MPump, a proprietary pump with inherent safety features that make it ideal for use in pediatric bypass surgery.

Susan Alpert, Ph.D., M.D.

(Retired from Medtronic)
Former Senior Vice President - Chief Regulatory Officer

Susan Alpert, Ph.D., M.D. joined Medtronic in July 2003 as Vice President of Regulatory Affairs and Compliance. In this role, she was responsible for all Medtronic global regulatory efforts. Prior to joining Medtronic, Susan served C.R. Bard, Inc., as Vice President of Regulatory Sciences. She also previously worked at the FDA where she held a variety of positions in the Centers dealing with drugs, devices and radiological health, and foods, including six years as the Director of the Office of Device Evaluation. She is a microbiologist and pediatrician with a specialty in infectious diseases and has practical experience in laboratory research and clinical trials. Susan completed her undergraduate degree at Barnard College, Columbia University in New York City and holds a master's degree and Ph.D. in Biomedical Sciences from New York University. She received her medical degree from the University of Miami (Florida) and completed her clinical training at Montefiore Medical Center in the Bronx, New York and at Children's National Medical Center in Washington, D.C.

P. Brian Smith, M.D. MPH MHS

Associate Professor of Pediatrics, Duke Clinical Research Institute
Member, Pediatrics Trial Network Steering Committee

Dr. Smith completed his residency in pediatrics and fellowship in neonatology at Duke University Medical Center. He completed an MHS from Duke University in Clinical Research and an MPH in Biostatistics at the University of North Carolina Chapel Hill.
Dr. Smith is an Associate Professor in the Division of Neonatology and a faculty member at the Duke Clinical Research Institute.
Dr. Smith was employed at FDA (2006-2010) in the Office of the Commissioner as Senior Pediatric Consultant. Dr. Smith is Associate Director of the DCRI fellowship program and Chief of the Division of Quantitative Sciences. He leads a Department of Health and Human Services funded project implementing comparative effectiveness research in 300 Neonatal Intensive Care Units across the US. Dr. Smith is a member of the Pediatric Trial Network Steering Committee. His areas of research interest include the safety and dosing of therapeutic agents in children.

James J. Huttner, M.D., Ph.D

Co-Founder and Vice President, New Product Development, Bionix

James J. Huttner, M.D., Ph.D., is co-founder and vice president of new product development at Bionix Development Corporation, an innovative Ohio-based medical device company. For more than 25 years Dr. Huttner led the new product development efforts for Bionix while also operating his pediatrics practice. This unique insight into the needs of medical professionals and their patients has led to a full product line of innovative, patented medical devices that add value to everyday medical procedures. Dr. Huttner's inventions include the Lighted Ear Curette™, the Lighted Articulating Ear Curette and OtoClear® Ear Irrigation Tips.

Andre A. Muelenaer, Jr, MS, M.D.

President and CMO, PMDI, Pediatric Trials Network Device-Core Co-Chair, and Carilion Clinic Pediatric Pulmonology/Allergy Section Chief

Dr. Muelenaer is the President and Chief Medical Officer of the Pediatric Medical Device Institute, a 501(c)(3), non-profit organization, consisting of a consortium of ten children's hospitals, their university affiliations, and technology communities. He has managed commercialization projects for medical devices. He is currently co-managing or facilitating 14 projects at seven consortium institutions and eight small businesses. As a co-inventor of several devices, he understands intellectual property issues, design challenges, business relationships, manufacturing concerns, and marketing/distribution issues. He has won awards for leadership in the regional technology community of southwestern Virginia. He serves on the board of directors of commercial enterprises; non-profit service organizations at the local, regional, national, and international levels, and of several professional societies. Within the discipline of pediatric pulmonology, his primary area of interest is in lung and respiratory control disorders of the preterm infant. In addition to his clinical, research, business, and entrepreneurial experiences, Dr. Muelenaer has served internationally as a medical consultant for delivery of medical and humanitarian care in Central Asia and Africa. He has also worked in the global healthcare market with biomedical companies involved with many aspects of medicine.

Robert H. Bartlett, M.D.

Professor Emeritus, in the Section of General Surgery, Division of Acute Care Surgery at the University of Michigan

Dr. Bartlett continues to be active in the lab and in clinical research. Prior to becoming Professor Emeritus on July 1, 2005, Dr. Bartlett was Director of the Surgical Intensive Care Unit, Program Director of the Surgical Critical Care Fellowship and Director of the Extracorporeal Life Support Program at the University of Michigan Medical Center and is best known for developing the extracorporeal membrane oxygen machine, or ECMO, a modified heart-lung machine used around the world for patients with acute heart or lung failure. He received his medical degree from the University of Michigan Medical School, cum laude in 1963. He was on the faculty at the University of California, Irvine, 1970-1980, and has been at the University of Michigan since 1980. Dr. Bartlett has been the recipient of many awards and honors over the last thirty years. In 2002, he was awarded the Medallion for Scientific Achievement from the American Surgical Association. In 2003, Dr. Bartlett received the Ladd Medal of the American Academy of Pediatrics and the American College of Surgeons Jacobson Award. In addition, he was honored with two inductions: the National Institutes of Health Great Clinical Teachers Series and the Institute of Medicine of the National Academy of Science.

Daniel Teitelbaum, M.D.

Professor, Surgery CS Mott

Dr. Teitelbaum is a Professor of Surgery at the C.S. Mott Children's Hospital and the Medical Director for HomeMed and MedEquip for the University of Michigan. He received his medical degree at the Ohio State College of Medicine and Columbus Children's Hospital. He began his work at the University of Michigan as an Assistant Professor of Surgery in 1992, became an Associate Professor in 1999, and a full Professor of Surgery in 2004. Dr. Teitelbaum has board certification in Pediatric Surgery, Surgical Critical Care, and General Surgery. His clinical interests include a wide-range of general, pediatric surgeries. He has a particular interest in surgery for Hirschsprung's disease, ambiguous genitalia, short bowel syndrome, and intestinal failure. Dr. Teitelbaum is funded for development of a bowel-lengthening medical device by FDA-granted Michigan Pediatric Device Consortium (M-PED).

Brad Slaker, M.B.A.

Founder, CEO and Chairman of the Board, DesignWise

Slaker brings over 20 years in the for-profit medical device industry, including extensive experience in all aspects of medical device product development from concept generation, product development and refinement, regulatory submissions, quality system requirements, manufacturing development, surgeon/physician relationships, project management and the management of engineering staff and cross-functional project teams. He also holds seven patents for various medical devices. Slaker has a B.S. in mechanical engineering from the University of Minnesota and his MBA from the University of St. Thomas.

James Geiger, M.D.

Professor of Surgery at the University of Michigan

Dr. James Geiger, Professor of Surgery at the University of Michigan serves as a pediatric surgeon at C.S. Mott Children's Hospital and is recognized as a world's expert in the area of advanced laparoscopic surgery and robotic surgery techniques. His vast surgical interests include inflammatory bowel disease, oncology, liver surgery, and portal hypertension. He has extensive experience with investigator-initiated (IND) pediatric clinical trials in cancer immunotherapy. As Co-Founder and Executive Director of the Medical Innovation Center (MIC), he provides medical mentorship to the current MIC Innovation Fellows. He is developing and commercializing a number of medical devices and has been involved in global device innovation projects, has been a co-PI on Gates Foundation grants, and is involved in a device being developed for international markets such as Ghana. Dr. Geiger directs the CS Mott Children's Minimally Invasive Surgery Program and is Surgical Director of the Pediatric Comprehensive Weight Management Center. He earned his medical degree from Case Western Reserve University School of Medicine and completed his residency and fellowships at the University of Michigan Health System. He is board-certified in pediatric surgery, general surgery, and surgical critical care. Dr. Geiger also is an active participant in the University of Michigan's Collaborative Research Program with Shanghai Jiao Tong University and Peking University in China.

University of Michigan Health System

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M-PED Pediatrics Device Consortium

Larry Schmitt, Ph.D.

President, The Inovo Group

During the past decade, The Inovo Group has emerged as a leading innovation consulting firm for technology-inspired organizations. Under Larry's leadership, Inovo has helped numerous Global 1000 companies (including Corning, Dow, Ford, Henkel, Medtronic, and Nestle Purina) to identify areas of significant opportunity and develop new-to-the-world products, services and business models.

Larry has spoken about innovation to audiences in the US and India, and he has taught courses on Innovation to MDs, MBAs, Engineering PhDs, and graduate students at the University of Michigan's Medical Innovation Center, College of Engineering, and Ross School of Business.

Earlier in his career, Larry held both technical and managerial positions with multinational corporations including General Electric and Unisys. He subsequently served as an executive at two successful tech startups: Applied Intelligent Systems, Inc. (acquired by Electro-Scientific Industries) and Intelligent Reasoning Systems, Inc. (acquired by Photon Dynamics). Larry holds a BS in Computer Science from the University of Michigan, Ann Arbor, and an MS and PhD in Computer Science from the University of Wisconsin, Madison.

Anil Mankodi

Program Director, Transcatheter Pulmonary Valve Development Programs Structural Heart, Medtronic Cardiac and Vascular

Anil Mankodi is currently working as the Core Team Leader for Transcatheter Pulmonary Valve development programs with the Structural Heart group of Medtronic Cardiac and Vascular division. Anil has more than 23 years of experience in the field of medical devices having worked in various geographies (India, Canada and USA) in leadership positions for project management and marketing. Understanding un-met clinical needs and developing transcatheter treatment options for congenital heart diseases impacting pulmonary valves, are areas of his current focus. Anil has a bachelor's degree in Mechanical Engineering and a Masters in Business Management.

We are still accepting speaker recommendations and as noted in the Agenda, we will be soliciting and accepting nominations for our Pediatric Innovator Awards. If you have recommendations, please contact

2012MICSummit@pulse220.com

The 2012 MIC Summit will be held at:

Sheraton Ann Arbor Hotel
3200 Boardwalk, Ann Arbor, MI 48108

Hotel rooms are available for the conference at a guaranteed group rate of $119 per night (plus taxes), but must be booked by February 18, 2012. A limited number of rooms are available at group rate, so call soon.

To book a room, please call the hotel's group reservation line at 1-888-627-7098.

PLEASE REFERENCE U-M MIC SUMMIT 2012

Registration Form

Online: www.med.umich.edu/ummic/about/summit.shtml

By Fax: MIC Summit, 248.263.6310

By Mail: MIC Summit
c/o pulse220
24463 W. Ten Mile Rd.
Southfield MI, 48033

Cut along lines to mail or fax

Registration Deadline: March 1, 2012

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p.m.d.i. Pediatric Medical Device Institute

In 2009 U-M M-PED was awarded a 2.2M dollar grant from the FDA for pediatric device development. In 2011, the collaborative M-PED-PMDI consortium was awarded an additional 2.3M dollar award for device development.

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