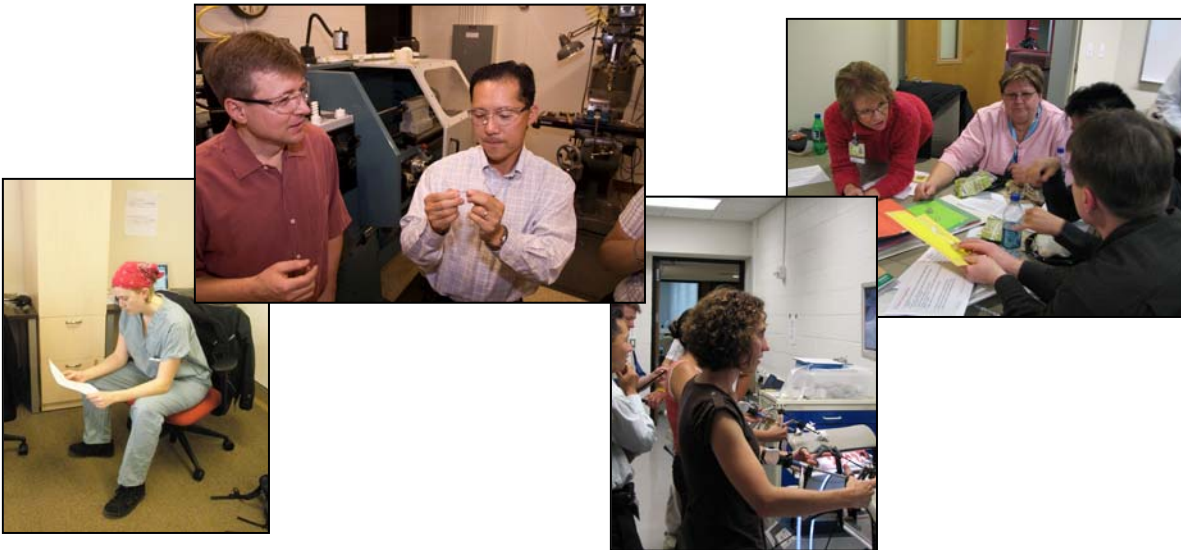


M-PED Consortium for Pediatric Devices



OVERVIEW

The University of Michigan Pediatric Device Consortium (M-PED) brings together a collection of assets rarely found together on one campus:

- top-ranking schools of
 - business,
 - engineering,
 - nursing,
 - dental and
 - medicine
- side-by-side with
 - one of the nation's finest children's hospitals and
 - other major facilities of a world-renowned health system.

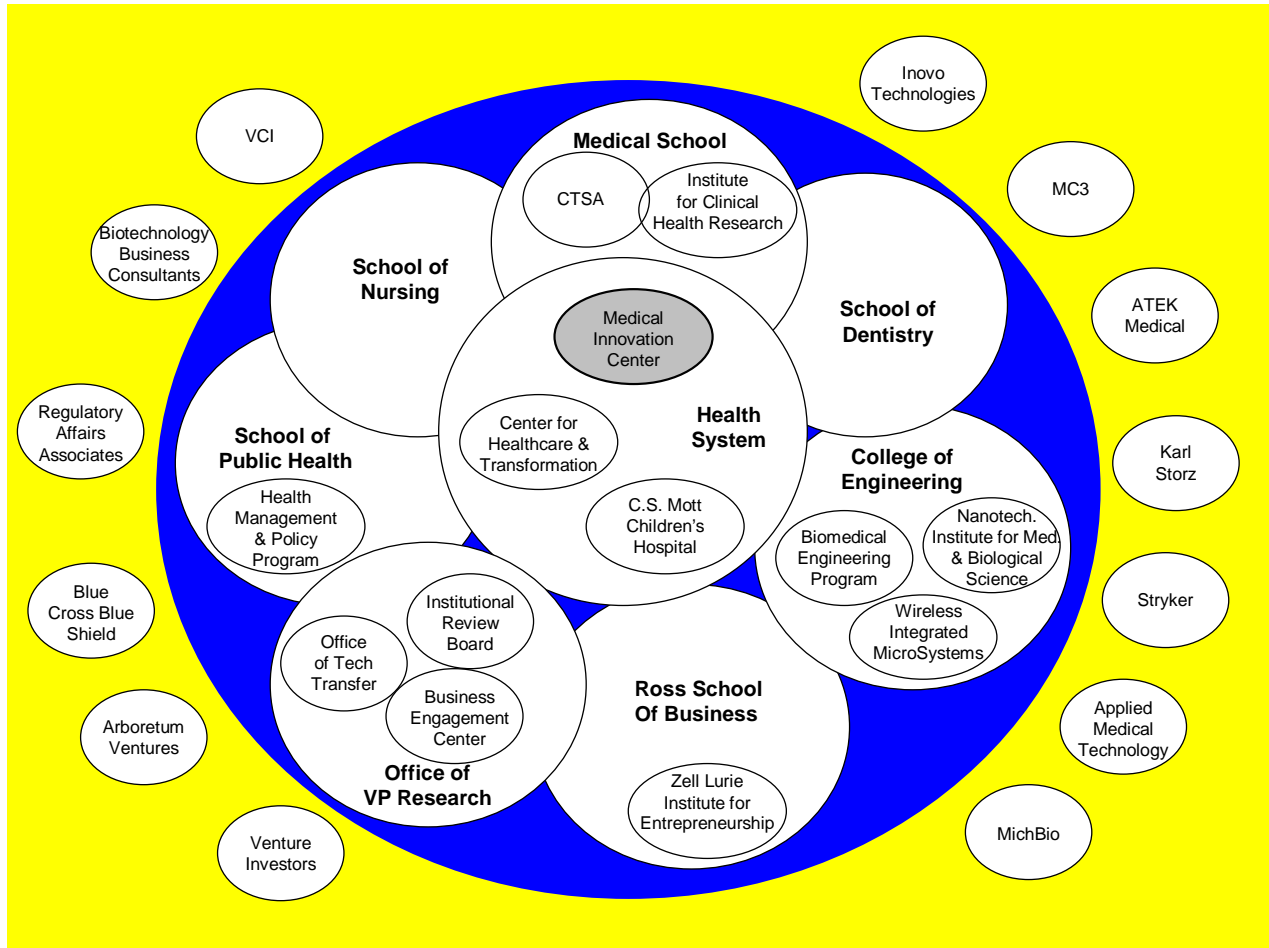
The Consortium will be managed by the Medical Innovation Center (MIC), a multi-disciplinary collaborative effort launched in 2008. Pediatric device innovators will be supported through the MIC's existing Inventor Assistance Program.

<http://www.med.umich.edu/ummic/pdf/InventorAssistanceProgram.pdf>

And, during their one-year, full-time fellowship program, the 2011 MIC Fellowship Class will develop solutions for unmet clinical pediatric device needs. Other important Consortium activities include

- a Pediatric Technical Advisory Group that will validate unmet clinical needs before investing time and resources into solutions,

- the development and distribution of standardized practices to facilitate pediatric device innovation more broadly, and
- the collaboration of the members of the area's medical innovation ecosystem (below) to overcome barriers unique to the commercialization of pediatric devices.



Objectives

The Consortium's membership, leadership and activities are designed to advance pediatric device development by accomplishing the following goals:

1. Advance the two pediatric device projects identified for funding by this P50 grant.
2. Advance additional pediatric device projects beyond the five detailed in this application.
3. Transform a group of post-graduates into pediatric innovators.
4. Identify, characterize and prioritize significant unmet pediatric needs.
5. Provide assistance and education to innovation-minded faculty, clinicians, students and staff.
6. Produce information "assets" on topics critical to pediatric device commercialization.

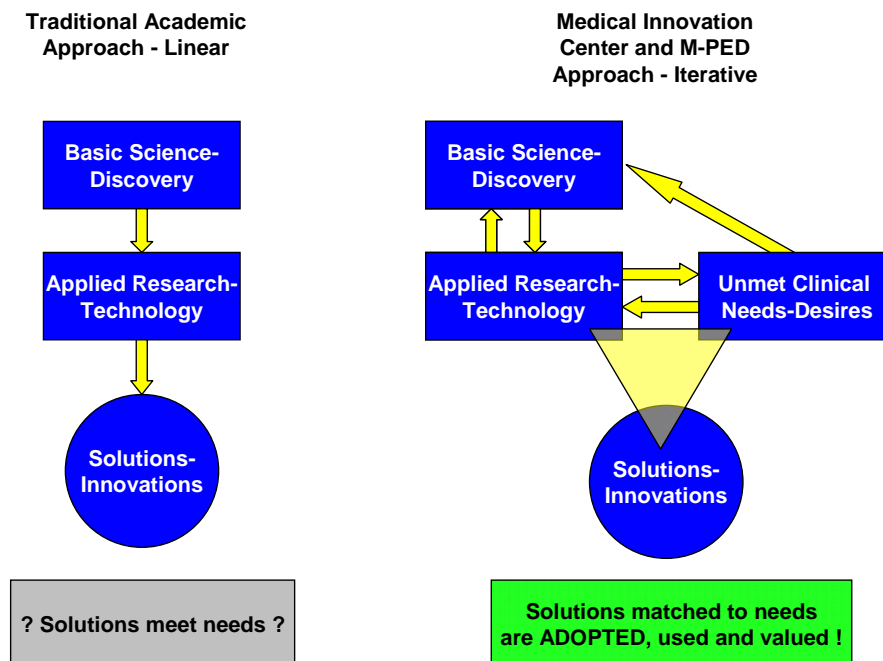
1. Advance the two pediatric device projects identified for funding by this P50 grant. The Consortium will leverage the MIC's existing Inventor Assistance Program to proactively manage these two projects:

- **Use of Distractive Forces to Induce Small Intestinal Lengthening** - The overall goal of this project is to develop a refined, implantable device which will lengthen the small intestine in children who suffer from short bowel syndrome (SBS). (Dr. Dan Teitelbaum, Professor Diann Brei, Professor Jonathan Luntz)
- **Nonthrombogenic Antiseptic Catheters for TPN for Children** - The overall goal if this project is to develop small intravascular catheter for neonates to address the clotting and infection problems with catheters in children. (Dr. Bob Bartlett and Dr. Gail Annich)

2. Advance additional pediatric device projects beyond the two detailed in this application. The Consortium will leverage the MIC's existing Inventor Assistance Program to proactively manage other promising pediatric device projects as determined by the Pediatric Technical Advisory Group.

3. Transform a group of three post-graduates into pediatric innovators. We will recruit a dedicated, multidisciplinary team of Pediatric Innovation Fellows into a one-year fellowship focused on pediatric device commercialization. These post-graduates will possess backgrounds in engineering, business and medicine (clinicians-MD, DO, DDS). This educational program will be based on the approach and curriculum already in use at the MIC for our current class of fellows. <http://www.med.umich.edu/ummic/fellowship/index.shtml>

4. Identify, characterize, and prioritize significant pediatric unmet needs. Traditionally in universities and academic medical centers, discovery and the development of new technology in "basic science" is encouraged by the desire to advance knowledge. This type of research is typically fueled by grants and rewarded by presentations, publications, promotion and reputation. Universities also engage in applied or "translational" research which is more focused on solving specific clinical problems. Sometimes this research involves *attempts* to commercialize the technology. These attempts are *sometimes successful*, but in other cases, scientists have developed a technology that is essentially a "hammer looking for a nail." The disconnect here is that these attempts at commercialization are not based on satisfying an unmet needs.



Great innovations come from understanding unmet needs and desires of patients, clinicians, etc., both articulated and non-articulated. If you match applied research programs with a thorough understanding of the unmet needs, you achieve greater success moving value into the marketplace to impact health.

It is difficult to truly understand needs by asking a group of pediatricians or pediatric experts their opinions in focus groups outside the clinical environment. On the contrary, understanding needs requires an intensive, formalized process based on immersing or embedding oneself into the clinical environments to make first hand observations of potential needs (i.e., watching a surgeon modify a device before using it on a patient or observing a pediatrician struggle to evaluate the middle ear). The innovation process also involves interviewing patients, nurses, physicians, purchasing personnel and device manufacturers as well as mining the medical literature, databases, the web, and important other resources.

This is the practical, hands-on innovation approach currently in use by the current MIC fellowship class.

5. Provide assistance and education to innovation-minded faculty, clinicians, students and staff.

The Consortium will leverage the MIC's existing Inventor Assistance Program to proactively assist faculty, clinicians, students and staff who have pediatric device ideas.

<http://www.med.umich.edu/ummic/pdf/InventorAssistanceProgram.pdf>

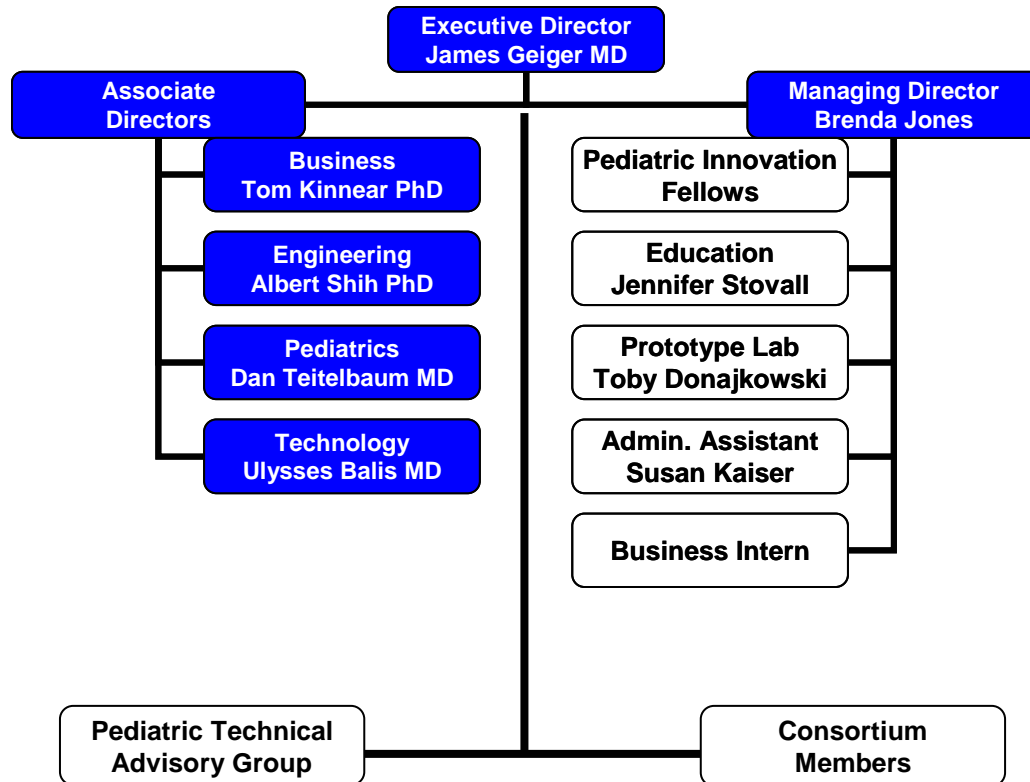
The education and services provided to these individuals are critical to the sustainability of the momentum of the Consortium, ensuring the continued development of pediatric device ideas. The more people who know how to manage the barriers to pediatric device commercialization, the more ideas they will generate and advance.

6. Produce information “assets” on topics critical to pediatric device commercialization.

The Consortium will enhance the MIC's existing portfolio of educational tools by producing information assets (e.g., on-line training modules, “best practices” documentation) to help educate and assist medical innovators.

Organization

M-PED Consortium Organization



Leadership

The leadership structure of M-PED reflects the need to have clinical, engineering and business experts collaborating on innovative ideas. The Consortium leadership will set Consortium strategy, lay out the Consortium execution plan as well as monitor the progress of the consortium and the individual projects. Of course, as issues arise, more frequent impromptu interactions will occur. The four Associate Directors will also serve on the Pediatric Technical Advisory Group (detailed later) and will have responsibility to cultivate pediatric device projects in their own programs.

James D. Geiger, MD, Executive Director - Dr. Geiger, Associate 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. 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. An inventor in his own right, he has developed and commercialized a pediatric device now being marketed by Karl Storz (Consortium member). Dr. Geiger will provide the overall strategic direction for the M-PED Consortium, serve as medical mentor to the Pediatric Innovation

Fellows and chair the Pediatric Device Technical Advisory Group, the body that evaluates the technical, clinical and commercial merit of pediatric device ideas.

Brenda Jones, MBA, Managing Director - Ms. Jones, Managing Director of the MIC, has drawn on her 20 years of business operations and management experience to launch the MIC. As the Managing Director of the Consortium, she will manage all operational aspects including financial controls, development of information “assets,” Consortium membership, the Pediatric Technical Advisory Group, Consortium activities and the Inventor Assistance Program.

Albert Shih, PhD, Associate Director Engineering - Professor Shih, Co-Founder of the MIC and Professor of Mechanical Engineering and Biomedical Engineering, co-directs the S.M. Wu Manufacturing Research Center at the University Of Michigan College Of Engineering. He has extensive expertise in design and manufacturing, biomedical device design, biomedical manufacturing, surgical thermal management, machining of advanced engineering materials, and micro manufacturing. He also serves as the Associate Director of Engineering for the MIC. Dr. Geiger and Dr. Shih’s collaboration around medical devices has led to the commercialization of a pediatric device and served as the foundation for the formation of the MIC. As the Consortium’s Associate Director of Engineering, Professor Shih will serve as an engineering mentor to the Pediatric Innovation Fellows.

Daniel Teitelbaum, MD, Associate Director Pediatrics - Dr. Teitelbaum, Professor of Surgery at the University of Michigan, serves as a pediatric surgeon at C.S. Mott Children’s Hospital and is recognized globally as an expert in Hirschsprung’s disease and Short Bowel Syndrome. Dr. Teitelbaum has extensive experience in truly translational research including IND clinical trials. As a member of the MIC Technical Advisory Group, he has provided clinical and commercialization advice to inventors who have come to the MIC for assistance. He currently directs the research and commercialization activities for several pediatric device ideas one of which was selected as a project to be supported by this grant. As the Consortium’s Associate Director of Pediatrics, Dr. Teitelbaum will work closely with Dr. Geiger in all aspects of the M-PED consortium.

Thomas Kinnear, PhD, Co-Investigator, Associate Director Business - Professor Kinnear, Chair of the Marketing Department at the Ross School of Business Administration at the University of Michigan, serves as the Executive Director of the Zell Lurie Institute for Entrepreneurial Studies. For many years, has served as an advisor, investor, and board member in start-up companies in the technology and biotechnology sectors. As the Consortium’s Associate Director of Business, Professor Kinnear will serve as a business mentor to the Pediatric Innovation Fellows and will provide business creation strategic advice to the 5 pediatric projects.

Ulysses Balis, MD, Co-Investigator, Associate Director Technology - Dr. Balis, Associate Professor of Pathology, directs Clinical Informatics at the University of Michigan. Dr. Balis was a Whitaker Foundation Fellow in the B.E.R.E. Program at Massachusetts General Hospital and the Harvard University Health Sciences and Technology Program. Dr. Balis is an inventor and technology expert who is the recipient of several awards including the Lansky Award from the College of American Pathologists (2000) for his efforts with establishing a DICOM image object descriptor (IOD) for use with digital microscopy. As a member of the MIC Technical Advisory Group, he has provided clinical and commercialization advice to inventors who have come to the MIC for assistance. As the Consortium’s Associate Director of Technology, Dr. Balis will provide critical evaluation of technology for the Pediatric Innovation Fellows and pediatric projects.

M-PED Consortium Members

The M-PED Consortium includes members whose expertise and experience cover all the issues relative to the commercialization of pediatric devices. The team will attack specific barriers and provide the groundwork for the information “assets” developed by the Consortium. The membership as a whole will set the agenda for the annual Pediatric Innovation Forum and engage with pediatric device project teams on an “as needed” basis.

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|--|--|---|--|
| <p>Needs Identification Process</p> <p>Brenda Jones, U-M MIC James Geiger, U-M MIC Larry Schmitt, Inovo</p> | <p>Device Research And Development</p> <p>Scott Merz, MC3 Lisa Kurek, BBC Steve Rapundalo, MichBio Bob Bartlett, UMHS U-M OVPR</p> | <p>FDA Approval and Compliance</p> <p>Steve Goldner, RAA Norm Howe, VCI Kay Fuller, MICH U-M IRB</p> | <p>Philanthropic Funding</p> <p>Christy Bieber-Orris, ATEK Ann Verhey-Henke, U-M Dev James Thomas, U-M Dev U-M Development Office</p> |
| <p>Pediatric Clinical Practice Needs</p> <p>James Geiger, UMHS Dan Teitelbaum, UMHS Gregory Yanik, UMHS Jerry Johnson, BCBSM</p> | <p>Device Manuf., Distrib. & Post Market Surv.</p> <p>Christy Bieber-Orris, ATEK David Chatenever, Karl Storz George Picha, AMT Bob Bartlett, UMHS Steve Rapundalo, MichBio</p> | <p>Clinical Trial Design & Execution</p> <p>Steve Goldner, RAA Gregory Yanik, UMHS Scott Merz, MC3 U-M IRB</p> | <p>Federal Funding</p> <p>Lisa Kurek, BBC Scott Merz, MC3 U-M MICH U-M OVPR</p> |
| <p>Engineering and Prototyping Solutions</p> <p>Albert Shih, U-M COE Kahlil Najafi, U-M COE Toby Donajkowski, U-M MIC Scott Merz, MC3</p> | <p>Intellectual Property And Licensing</p> <p>Robin Rasor, U-M OTT James Bertolina, U-M OTT Jeff Schox, Schox PLC</p> | <p>Reimbursement And Insurance</p> <p>Steve Goldner, RAA Jerry Johnson, BCBSM</p> | <p>Venture Funding</p> <p>Tom Kinnear, U-M ZLI Tim Faley, U-M ZLI Jim Adox, Venture Investors Paul McCreadie, Arboretum U-M OTT</p> |

Inovo Technologies, Inc., is an innovation consulting company that works with organizations in all industries and all sizes, from Fortune 500 to start-ups, to help them become more innovative. The company was founded in 2001 and is headquartered in Ann Arbor, Michigan. Its not-for-profit subsidiary, Inovo Institute, provides discounted education and consulting to not-for-profit organizations and small venture firms. **Larry Schmitt PhD**, co-founder of Inovo, has been working with innovative companies to create competitive advantage and market leadership for over 35 years. His career-long involvement and interest in identifying the new opportunities that arise from emerging customer needs and new capabilities has been the foundation of Inovo.

Michigan Critical Care Consultants, Inc. (MC3) identifies promising early-stage technologies for medical devices and develops them from concept to commercialization. The company is based in Ann Arbor, Michigan. **Scott Merz PhD**, MC3 CEO, co-founded the company when he was a graduate student in biomedical engineering at the University of Michigan. At the time he was working in the lab of world-renowned surgeon, Bob Bartlett MD (Consortium and PTAG member) where he and several other students developed a blood pump for cardiac surgery.

Biotechnology Business Consultants (BBC) has received funding from the Michigan Technology Tri-Corridor Fund and the 21st Century Jobs Fund to provide commercialization consulting services to technology entrepreneurs and early-stage technology companies throughout Michigan. Through a combination of seminars, training sessions, one-on-one

meetings and intensive consulting assistance (incubation services), BBC assists entrepreneurs and early-stage technology companies to progress toward the goal of commercialization of novel products and technologies with the following services: SBIR/STTR Grant Development Assistance, Business Development Consulting for Life Sciences and Statewide Outreach. BBC's partners have held senior management positions with a number of successful life science companies over the past 25 years in disciplines ranging from medical devices and diagnostics to biotechnology tools and technologies. **Lisa Kurek MS**, Managing Partner of BBC, possesses extensive experience in the biomedical technology field. She spent 15 years in product development, sales, sales management, product management and business development within the industry.

MichBio is the biosciences industry trade association and the official Michigan affiliate of the Biotechnology Industry Organization, BIO, which represents biotechnology companies across America and in 33 other nations. Formed in 1993 as the Michigan Biosciences Industry Association, MichBio promotes cooperation between Michigan's bioscience-related businesses, forges stronger relationships, develops business-to-business opportunities and serves as a united industry voice to improve the overall science-friendly environment for attracting and founding new business. MichBio members are bioscience-related companies, research institutions, hospitals, public universities and their technology transfer offices, service providers, and economic development organizations interested in furthering the expansion of the biosciences and business climate in Michigan. **Steve Rapundalo PhD**, President and CEO of MichBio, has broad experience in the life sciences, with an extensive background in pharmaceutical research and development. Prior to his appointment as Executive Director of MichBio in April 2006, he spent almost 20 years as a senior research scientist, project manager, and group leader with Parke-Davis Pharmaceutical Research and then Pfizer, Inc., primarily in the area of cardiovascular drug discovery.

Regulatory Affairs Associates (RAA), founded in 2001, provides professional services to organizations to obtain regulatory approval (FDA and EMEA) and insurance reimbursement of drugs and medical devices. In addition to regulatory advice, this Michigan-based company also offers services related to biocompatibility, clinical trial management, legal matters, GMP and GCP compliance, SOPs, physician sample procedures, labeling and recall management. **Stephen Goldner, JAD RAC** is the founder and principal officer of RAA. A chemist and an attorney by training, Steve has more than 30 years of experience as a regulatory professional. Throughout his regulatory career, Steve has developed both a strong track record of success and strong working ties with the FDA. These interactions have included work on NDA/ANDA, 510(k), and IND submissions, QA/QC validation and insured GMP compliance.

Validation and Compliance Institute, LLC (VCI) provides a full range of validation and compliance services for the FDA regulated industries. This Michigan-based company has experience in current Good Manufacturing Practices (cGMP) for Pharmaceuticals, Medical Devices, Active Pharmaceutical Ingredients, Food and Beverage, Biopharmaceuticals, Sterile fill, Excipients and Computer software validation. **Norm Howe PhD**, VCI Senior partner, has held many management positions in the life sciences industry, most in production at BASF. He has lead teams that have developed more than a dozen new products and installed more than \$60M in capital. He is an adjunct Professor of Regulatory Science at the University of Michigan and has authored articles on compliance, chemistry, and general management.

ATEK Medical is a Michigan-based private, certified woman-owned contract manufacturer for medical devices offering full product service from concept through product launch and ongoing production. Their product line includes disposable, implantable, and electromechanical medical

devices. **Christy Bieber-Orris BS MBA**, the CEO of ATEK Medical's parent company, has recently launched a *Philanthropic Foundation for Pediatric Devices*.

Blue Cross Blue Shield of Michigan (BCBSM) is a nonprofit organization providing and administering health benefits to 4.6 million Michigan residents. In 2008, BCBSM earned an eValue8 Health Plan Innovation Award from the Washington, D.C.-headquartered National Business Coalition on Health for the groundbreaking Value Partnerships program. The award recognizes the Blues' national leadership in collaborating on joint programs with physicians and hospitals that have led to improved health care for millions of Michigan residents, and enhanced health care value and efficiency. **Jerry Johnson MD**, Senior Medical Director of BCBSM, is a pediatrician and internist by training and as served as the Clinical Lead on BCBSM's medical policy/new technology assessment committee for the last six years.

KARL STORZ, founded in 1945 in Germany, has established itself worldwide as an international and highly regarded company in the production and sale of medical instruments and devices. Its range of endoscopic equipment for human and veterinary medicine and for industrial applications now encompasses over 8,000 products. New developments such as the OR1™ fully networked operating room or the KARL STORZ AIDA centralized image and data management system supplement the range and demonstrate that at KARL STORZ, the future has already become the present. **David Chatenever PhD**, Vice President of Product Development, spearheaded the commercialization of the pediatric pyloric clamp co-invented by Dr. James Geiger and Professor Albert Shih at the University of Michigan.

Applied Medical Technology, Inc. (AMT) is an Ohio-based developer and manufacturer of niche medical and surgical products including *a line of pediatric devices*. These products are distributed worldwide in a wide variety of markets. AMT has been developing and manufacturing medical devices for over 20 years through OEM agreements with major medical corporations. **George J. Picha, MD PhD FACS**, AMT founder and CEO, is a practicing physician and entrepreneur.

Stryker Corporation is a publicly traded medical device manufacturer with a broad product line encompassing surgical devices, OR equipment, orthopaedics and medical software. Headquartered in Michigan, the company was named by *Fortune #6* most admired company in the medical and other precision equipment industry. **Brent Ladd**, Director of Marketing, has interacted with the University of Michigan on several technology projects.

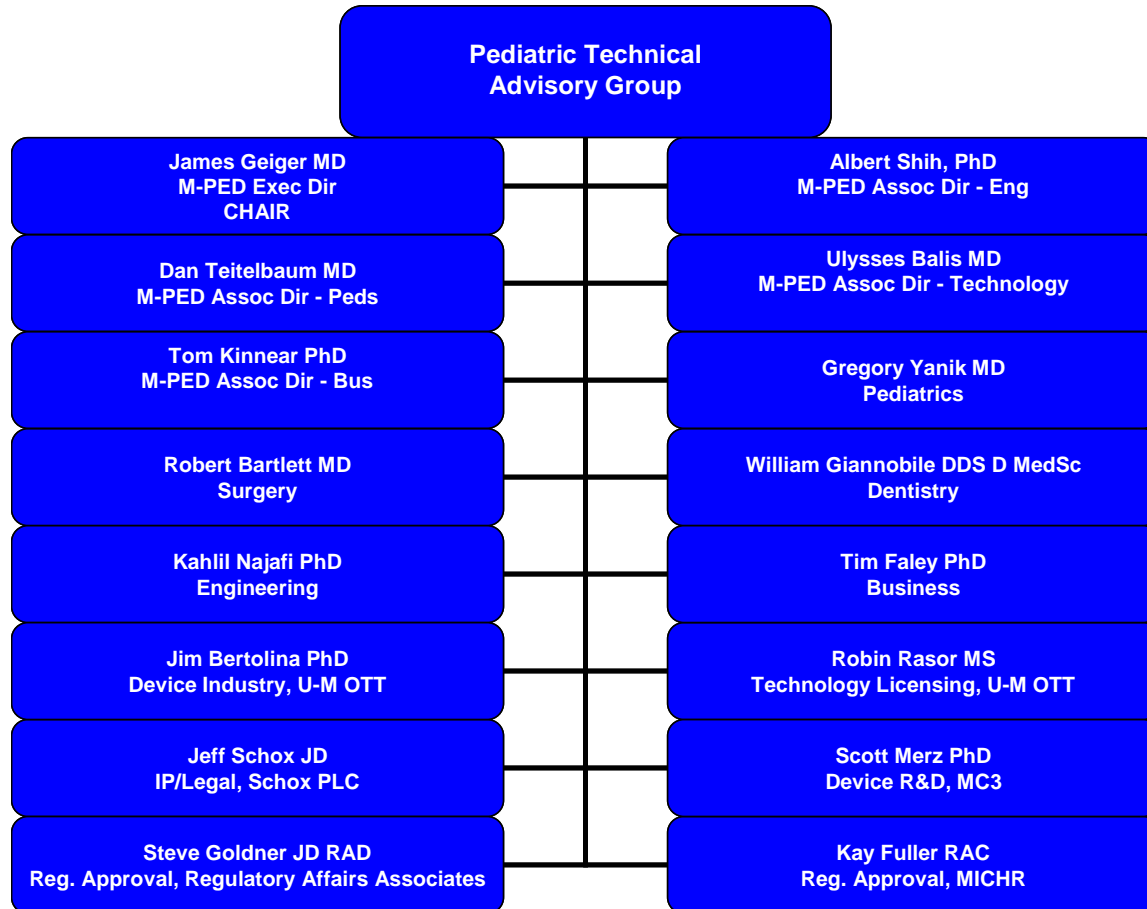
Schox PLC builds patent portfolios for startup ventures that enable them to build value and attract funding. Founder **Jeff Schox JD** specializes in medical devices.

Venture Investors was founded in 1982 and is one of the leading venture capital firms in the Midwest. They focus on making seed and early stage healthcare and technology investments, and have spun-out 20 companies from leading Universities. The firm is currently investing out of its fifth fund and has over \$200 million under management.

Arboretum Ventures is an early-stage venture capital firm specializing in the healthcare sector. They focus primarily on investments in medical technology and healthcare services. Arboretum invests throughout the United States, with a special interest in the Midwest region. Founded in 2002 and located in Ann Arbor, Michigan, Arboretum currently manages \$95 million in capital.

Pediatric Technical Advisory Group

The Pediatric Technical Advisory Group (PTAG) will evaluate the technical, clinical and commercial merit of pediatric device ideas and identify U-M, industry and other collaborators and key community resources. The PTAG will provide critical advice on commercialization strategy and venture funding and will help make “kill” decisions on projects that develop barriers that cannot be overcome, thereby saving valuable resources and time.



Gregory Yanik, MD, Professor of Pediatrics and Communicable Diseases at the University of Michigan, focuses his research in the areas of biology and treatment of acute lung injury following bone marrow transplant, development of new strategies for treating AML and the biology and treatment of neuroblastoma. Dr. Yanik has extensive experience in the design and conduct of clinical trials in children. Dr. Yanik will provide assistance in understanding pediatric needs, identify other pediatric collaborators and help plan clinical trials.

William V. Giannobile, D.D.S., D.Med.Sc. is the Najjar Endowed Professor of Dentistry and Biomedical Engineering and is also the Director of the Michigan Center for Oral Health Research at the School of Dentistry. Dr. Giannobile has published and lectured extensively in the fields of Regenerative Medicine, Tissue Engineering, and Salivary Diagnostics as it relates to periodontal and peri-implant reconstruction. Dr. Giannobile will mentor Dental graduate

students working at Medical Innovation Center and assist in the understanding of unmet pediatric dental needs.

Robert H. Bartlett, MD is an Emeritus Professor of General and Thoracic Surgery at the University of Michigan. His laboratory research on artificial organs has been continuously supported by NIH for 30 years. Prolonged extracorporeal life support (ECLS, ECMO) is one of the products of that research. ECMO is used clinically to treat patients with acute respiratory and cardiac failure. Dr. Bartlett and the laboratory have been recognized by the presidency of ASAIO and ISAO, charter membership in the American Institute of Medical and Biological Engineering, the Gibbon Award of AMSECT, the Barney Clark Award of ASAIO, the Sheen Award and Ravdin Lectureship of ACS, and the Gross, Harken, Zollinger, and Fogarty Lectureships. He co-founded MC3, an Ann Arbor based product research and development company and Consortium member. One of Dr. Bartlett's many device innovations has been selected as a project to be supported by this grant.

Timothy Faley, PhD, Adjunct Professor of Strategy at the Ross School of Business Administration the University of Michigan, serves as the Managing Director of the Samuel Zell & Robert H. Lurie Institute for Entrepreneurial Studies, the world's leading university-based center for entrepreneurial studies. He also directly oversees the Wolverine Venture Fund, the largest, most active University-based venture fund of its type in the country. Professor Faley will serve as a business mentor to the Pediatric Innovation Fellows, assist in MBA intern recruitment, and will work closely with Tom Kinnear in developing business strategy

Khalil Najafi, PhD, Chair of the Department of Electrical and Computer Engineering at the University of Michigan, serves as the Deputy Director, National Science Foundation Engineering Research Center (ERC) for Wireless Integrated MicroSystems (WIMS) and the Director of Michigan's National Nanotechnology Infrastructure Network (NNIN). He will assist in identifying collaborators within WIMS for pediatric-related projects requiring this technology.

Jim Bertolina PhD, Mentor-in-Resident, U-M Office of Technology Transfer, possesses significant medical device industry experience including positions as Product Manager, Radiosurgery Applications, Howmedica Leibinger Inc.; Technical Director, Surgical Navigation, Stryker Inc.; and VP, New Product Development, Xoran Technologies Inc.

Robin Rasor MS, Director of Licensing, U-M Office of Technology Transfer, oversees staff handling all functions of the licensing process at the University ranging from management and marketing of disclosures to developing and negotiating appropriate licensing terms for license agreements, and finally to maintaining and monitoring existing agreements. Previously, Ms. Rasor was Director of Licensing at The Ohio State University.

Kay Fuller, RAC, IND/IDE Project Manager at Michigan Institute for Clinical Health Research (MICHR), manages the MICHR's Research IND/IDE Investigator Assistance Program (MIAP). She has provided regulatory training and advice to the current MIDC Fellows and other internal clients. She also serves on the MIC's Technical Advisor Group.