Driving MNOVATION Forward

What's on Deck

CTTC Services Spotlight: Marketing



Vanderbilt's Center for Technology Transfer and Commercialization provides professional commercialization services to the Vanderbilt community, thus optimizing the flow of innovation to the market and generating revenue that supports future research activities, while having a positive impact on the global society.



Message from the Director

Anyone Can Innovate

Alan Bentley

Assistant Vice Chancellor, Intellectual Property & Commercialization

When we think about inventions, discoveries, and the products derived from them, many tend to focus on outcomes from cutting-edge research in engineering and medicine. But innovation can happen anywhere, by anyone, at any time – as we are often reminded by the variety of inventions disclosed to CTTC each month.

In the 2014 fiscal year, CTTC fielded 185 disclosures from Vanderbilt faculty, staff and students. These new ideas came in the form of curricula, software programs, robotics, medical devices, chemical compounds, innovative uses of existing products - the list goes on. While the majority of disclosures were submitted by investigators within the major research-intensive departments within the schools of Arts & Science, Engineering, Medicine and

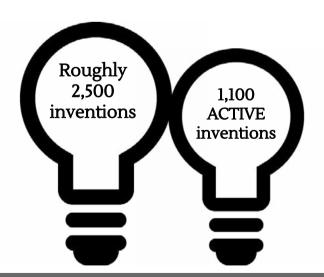
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Peabody, a number of disclosures originated from places one may not expect - the Office of Investments, Public Affairs, and the Department of Finance to name a few.

As they say, "necessity is the mother of invention." Creative innovation is the result of a deeply held desire to realize improvement in the world around us. A perfect example of this is in the work of this newsletter's featured inventor, Dr. Elisabeth Dykens, professor of psychology,

associate director of the Vanderbilt Kennedy Center for Research on Human Development, and co-director for the University Center for Excellence in Developmental Disabilities. Dr. Dykens piloted a three-year study that led to the development of two programs that aid parents of children with disabilities in learning how to reduce stress levels (known as "Mindfulness-Based Stress Reduction" and "Positive Adult Development", which are licensed together as part of the Parent Stress Intervention Program, or "PSIP"). PSIP was recently added to VU e-Innovations, our e-commerce site that licenses products directly to end-users. The program was also featured in the New York Times.

The take home message is that great ideas originate everywhere within an organization such as Vanderbilt, where there is a culture and commitment to innovation and improvement. At CTTC, we serve the entire Vanderbilt community. If you or one of your colleagues develops a novel program, tool, software application, or other form of innovation that might be the solution to a long-felt problem, or that just makes something work better, let us know – we may be able to help. Your idea may have a broader potential impact than you realize.







Stay Connected to CTTC

To stay informed of the latest innovation news, events and technology commercialization activities, visit our blog, CTTC Muse. There you will find everything from agreement signings to tips for inventors - such as how to publish and patent - to videos about Vanderbilt technologies and core research capabilities.

Featured Inventor

Elisabeth Dykens, Ph.D.

Annette Schaffer Eskind Chair Director of the Vanderbilt Kennedy Center

Professor of Psychology & Human Development, Psychiatry, and Pediatrics

Co-director of the Vanderbilt Kennedy Center for Excellence in Developmental Disabilities



It was an idea that literally flipped traditional research on its head. While most research programs look for ways to help children with disabilities, Elisabeth Dykens, Ph.D., director of the Vanderbilt Kennedy Center and professor of Psychology and Human Development, Pediatrics instead wanted to explore ways to help the *parents* of children with disabilities. And that is exactly what she and her team of researchers did in developing the Parent Stress Intervention Program (PSIP) with grant support from the National Institutes of Health.

"There are a ton of studies out there that describe how parents raising children or adult children with intellectual or developmental disabilities are stressed," said Dykens. "They are at higher risk for medical problems, for mental health issues. The deciding factor that moved me into this intervention program was a set of my own data on the cortisol trajectories of women raising children with autism and other disabilities. Most women had blunted trajectories, an indicator of chronic stress, and these women also had much higher levels of depression, anxiety, and stress, and that's exactly what we would have predicted. Seeing that data and realizing what it meant, I realized that I didn't want to describe anymore. I wanted to do something about it. So I made the move away from natural history or descriptive studies into an active intervention."

Dykens started by doing her homework. She took a class in positive psychology from which she was able to extract practices and lessons that she felt would be applicable to her intervention program. She then took a mindfulness based stress reduction class at the Osher Center for Integrative Health at Vanderbilt.

"My thinking was that for me to be able to teach others, or understand study results, I needed to be more familiar with what I was sharing and evaluating by going through it myself," said Dykens.

After completing her own series of trainings and classes, Dykens and colleagues launched a three-year program that studied the benefits of mindfulness based stress reduction practices for parents of children with disabilities. The goal was to train a team of peer mentors who would coach groups of parents through the techniques. Dykens hired parents of children with disabilities, trained them to deliver the curriculum, and at the same time, evaluate how well the peer model worked. The results were astonishing.

"The anecdotes and stories have been amazing," said Dykens. "Parents would say things like 'my life has been transformed,' or 'I can now go

"I wanted to do something that was just for the parents." - Elisabeth Dykens, Ph.D.

into the grocery story and before I used to sit in the car and weep.' Their heart-wrenching stories validated for me that the time is way overdue to move from descriptive to intervention studies."

While the goal of the study was to explore stress reduction for parents, Dykens said they did witness a trickle down effect and saw the children benefit from their parents practice of mindfulness techniques — their relationships grew stronger and often parents would practice the mindfulness techniques with their children which proved even more beneficial for the parents and children.

"Parents started telling us they were doing the mindfulness techniques with their children, and a light bulb went off," said Dykens, "In our third year of the program, we actually taught mindfulness practice to children and adults with all kinds of developmental disabilities while we worked with their parents in a separate room. The combination was very, very powerful."

In August, PSIP was made available to users on CTTC's e-commerce website, VU e-Innovations, In less than six months, the curricula has been licensed to more than 100 end users.

"Inventions come in all different forms and through different methods," said Dykens. "For this project, it didn't involve anything mechanical, it really came from the idea that for intervention to be effective in a chronically stressed, high risk population, you had to flip things on it's head."

Dykens said there are several programs in the works to expand on the initial study. One junior faculty member at the Vanderbilt Kennedy Center and Department of Pediatrics was recently awarded a grant to conduct mindfulness training in parents of children who are newly diagnosed as being on the autism spectrum. Dykens' research team is also in the process of analyzing data related to fathers of children with disabilities as well as treatment response from military families. Additionally, this summer, Dykens and colleagues will host a summer training session for parents of children with disabilities and potential peer mentors who are interested in learning the intervention curriculum.

Research collaborators and authors for this study are: Elisabeth M. Dykens, Ph.D., Roxanne Carreon, B.S., Marisa H. Fisher, Ph.D., Lynette Henderson, Ph.D., Warren Lambert, Ph.D., Nancy Miodrag, Ph,D., Gordon Peerman, D.Min., Karen Pilkerton, R.N., Carol Rabideau, L.C.S.W., Janet Shouse, B.J., Julie Lounds Taylor, Ph.D., and Kathy Woods, M.Ed.



Learn more: VU e-Innovations

Click to watch on YouTube.



Technology News

MDRAP makes rounds, hires new Regulatory Affairs Manager

Less than a year into its existence, Vanderbilt's Medical Device Regulatory Affairs Program is gaining steam. Led by CTTC Medical Director Dr. Ken Holroyd, the program aims to assist Vanderbilt investigators as they navigate federal guidelines and regulations surrounding medical device innovations.

MDRAP holds a Town Hall Forum

In October 2014, Holroyd (pictured below) hosted an MDRAP Town Hall Forum for the Vanderbilt community. A crowd of more than 30 gathered to learn about the program. Emphasis was placed on why MDRAP was formed, how it will assist investigators, and what investigators can expect as the program expands.



"It is very important for teams to call us early if they have any interest at all in what regulatory process might mean to your project," Holroyd told the crowd. "There are numerous timeline considerations, tasks to be completed, and funding opportunities that we can help investigators navigate. Hopefully, MDRAP can play a small role in helping make the grant programs and applications more effective."

Before fielding questions from the crowd, Holroyd outlined plans to reach out to various groups within Vanderbilt to learn how MDRAP can best coordinate with and support their program goals. These meetings began shortly after the town hall forum and will continue.

MDRAP hires Regulatory Affairs Officer

At the meeting, Holroyd informed the group that recruitment had begun for a Regulatory Affairs Officer to work alongside Lu Ellen Davie, MS, RN, MDRAP quality assurance manager. In December, Axel Strombergsson, M.Sc., joined Vanderbilt to serve in this capacity.

"Working at CTTC appealed to me because I want to continue to use my skills as a medical device expert in supporting the development of innovations and new products that, when released to the market, will help improve or even save people's lives," said Strombergsson. "The combination of working with interesting and fascinating technologies and at the same time being able to provide benefit to the healthcare sector is what I love with medical device research and development." Prior to joining CTTC, Strombergsson (pictured to the right) spent about 12 years in the medical device industry, primarily for Plasma Surgical, a medical device manufacturer developing and distributing an energy based surgical system.

DuringhistimeatPlasmaSurgical,Strombergsson held various engineering positions, starting as a development engineer and project manager, and later transitioning into managerial positions at the Swedish manufacturing site as well as the R&D department in Atlanta.



MDRAP solicits suggestions from researchers

MDRAP is in process of holding meetings with engineering and medical school faculty who are leading Vanderbilt's efforts in medical device research and development. The purpose of the meetings is to hear what types of services will help investigators and support their success on particular medical device projects.

From these meetings, five themes have emerged for faculty assistance:

- advice, often up to years in advance of a potential human investigation using a medical device, on how best to work with the IRB, including for IRB review of investigational protocols for their non-significant risk or significant risk status;
- advice on what pre-clinical work would be needed to achieve an Investigational Device Exemption (IDE) from the FDA, and the resource implications for the research group;
- assistance with grants in process or being applied for, with regulatory advice:
- · assistance with design control documentation and regulations; and
- assistance with interactions with the FDA.

To inquire about scheduling a meeting or presentation, contact <u>mdrap@</u> <u>vanderbilt.edu</u>.

MDRAP Functions Early regulatory input into R&D Development of regulatory strategies Assistance with IDE preparation and maintenance Education Information Collaboration

New Venture News

InvisionHeart wins NEXT Award for Healthcare Startup

InvisionHeart, LLC, a Vanderbilt startup company, was recognized as Nashville's 2014 NEXT Award winner for healthcare startups. Led by CEO Josh Nickols, Ph.D., InvisionHeart is commercializing a 12-lead mobile ECG system that can be used everywhere from skilled nursing facilities to home health care. The system was the brainchild of Vanderbilt Associate Professor in Biomedical Engineering and Physics Franz Baudenbacher, Ph.D., and Vanderbilt Associate Professor of Clinical Anesthesiology Susan Eagle, M.D., who co-founded InvisionHeart with Nickols.

"We were honored to be selected as a finalist," said Nickols. "We've been very focused on the development of the technology and the lead-up to our FDA application. Having this recognition in the midst of all of that was really exciting."

The NEXT Awards is presented jointly by the Nashville Area Chamber of Commerce and the Nashville Entrepreneur Center as a way to celebrate and recognize Nashville's most innovative companies and creative entrepreneurs.

"I'm truly impressed by the knowledge these NEXT Award winners have brought to their companies and the generosity with which they help other entrepreneurs to make the same journey," Michael Burcham, president and CEO, Nashville Entrepreneur Center said in a news release. "Their ability to identify needs in the marketplace and build companies around solutions is truly impressive."

But the NEXT Award isn't the only exciting news for InvisionHeart this fall. The new company recently submitted an FDA application for device approval. According to Nickols, the 2,100 page document "exhaustively covered all of the hardware testing, software verification and validation, and met all of the compliance criteria as mandated by the FDA." "It was a mountain of work!" said Nickols. "But it feels great to have that

part done. After pausing to catch our breath, we're looking forward to building out other aspects of our system."

Nickols said that while he and the rest of the InvisionHeart team feel good about this step, they also know that there is work to be done ensure the technology is equipped with the tools and features that other care providers will require.

"We do have a lot of work ahead of us," said Nickols, "but we are so excited about the possibility of taking our technology to the market in the coming year. This entire process has gone really fast, from when we first signed the option in 2013. We've only been able to do that because we have an amazing team of people who are so focused, namely the engineers and physicians at Vanderbilt."

According to Nickols, the go-to-market strategy will focus on home care, long-term care, skilled nursing facilities, and other smaller practices that will benefit from the extension of care that can be offered at a world-class facility like Vanderbilt University Medical Center. He hopes to begin marketing the technology in 2015.



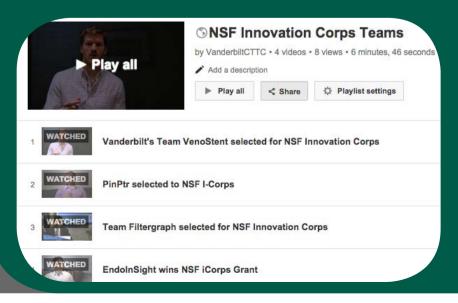
Above: Prototype of InvisionHeart's 12-lead smart ECG system.

Below (left to right): CTTC licensing officer Taylor Jordan and InvisionHeart CEO Josh Nickols at the initial option signing in 2013.



Five Vanderbilt teams selected to NSF Innovation Corps

CTTC's New Ventures Team has now successfully submitted five applications for the National Science Foundation Innovation Corps Program. The program aims to help scientists and engineers expand their NSF-funded research and explore commercial and startup potential. The five teams selected from Vanderbilt are: EndoInsight, School of Engineering; Filtergraph, School of Arts & Science; PinPtr, School of Engineering; VenoStent, School of Engineering and School of Medicine; and SMAC, School of Engineering.



Inventor Satisfaction Survey

You spoke, we listened!

The 2014 Inventor Satisfaction Survey showed overall growth in all areas of measurement, and the comments provided by Vanderbilt inventors identified both strengths of the office and areas ripe for improvement. Three themes from the responses stood out as areas of need.

Need more outreach to student and other non-traditional inventor groups.

Reaching out to potential inventor groups is an important part of CTTC's mission. Over the past year, CTTC has worked to provide greater outreach to many departments and centers to make sure that everyone who might need us, knows what services we offer and how to reach the office. That effort has led to a number of new invention disclosures and greater contact with faculty and staff.

During the 2015 fiscal year, CTTC will compile a list of the various student organizations and groups and reach out to them to see what kind of information should be provided. The office is also developing educational programs targeted at these non-traditional groups, including the Medical Center's ASPIRE program. Recently, CTTC piloted a new technology transfer rotation program for radiology residents, which may be expanded in the next year.

Need greater transparency on what you do and more frequent, timely updates.

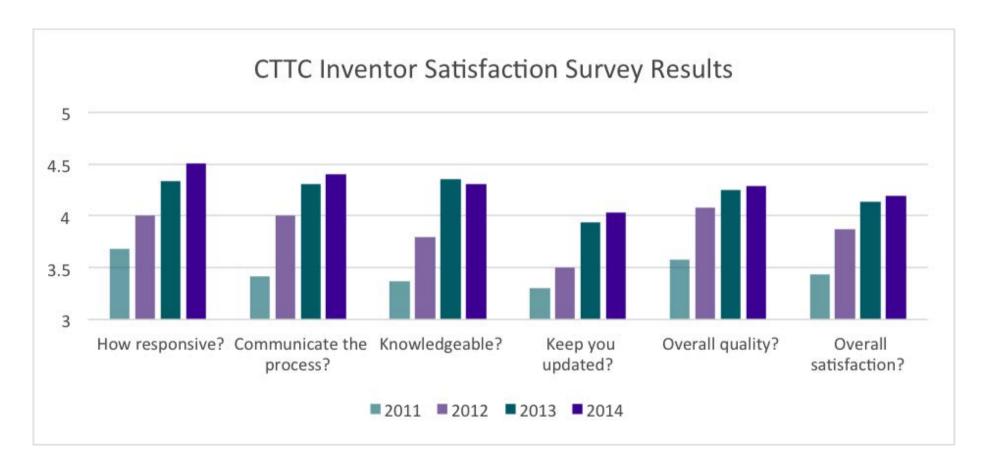
There are several internal initiatives underway that should help with transparency and communication over the next year. In 2012, CTTC refined and published our Commercialization Process to give inventors a better idea of what licensing officers do with your inventions when they are received, what you can expect as an inventor, and how you can get involved. The office is now working on adding more detail to that process to show inventors exactly what kinds of reports you will receive at various stages of evaluation, marketing and licensing. As these changes are implemented, CTTC will continue to look for other ways to improve responsiveness and updates regarding inventions.

Need a website for tracking inventions, stage of process.

This is a request that CTTC has been working to solve in a manner that will suit all inventors without creating a security or confidentiality risk. Internal infrastructure updates are currently in process. These updates will give us greater flexibility to create an "inventor portal" that will provide inventors with real-time information regarding disclosures and patent filings, as well as marketing contacts and licensing.

Focused on growth, improved services

CTTC continuously seeks ways to improve services to our inventors. The annual survey allows us to identify these opportunities and assess Vanderbilt's inventors level of satisfaction with our office and the services provided. For the third consecutive year, the 2014 survey showed improvements in all areas surveyed, including responsiveness, communication throughout the commercialization process, subject-area knowledge, and overall quality and satisfaction.

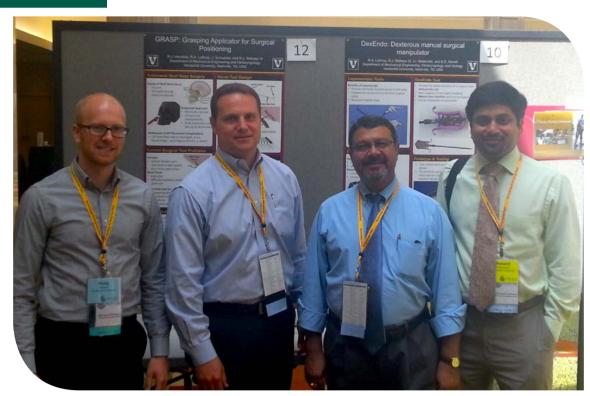


CTTC Services

CTTC supports Vanderbilt researchers who seek to commercialize intellectual property by providing a variety of services. Some of the services are more widely known, while others may be less obvious.

To give you an idea of how we can assist you, here is a snapshot of the services we regularly provide:

- Evaluating commercial opportunities and market potential for novel technologies
- Filing and prosecuting patent applications
- Marketing technologies to industry
- Negotiating license and option agreements
- Executing various agreements, including: license, material transfer, confidentiality, inter-institutional and research collaboration
- Facilitating sponsored research and clinical trial agreements
- Monitoring licensee compliance
- Tracking milestones and collecting royalties
- Distributing payments to inventors, labs, departments, centers, and schools
- Assisting in new venture assessment and development
- Educating through departmental talks and presentations about intellectual property protection and commercialization as well as educational seminars on commercialization-related topics



CTTC licensing team at the Southeastern Medical Device Association meeting (L to R): Phil Swaney, Taylor Jordan, J.D., Ashok Choudhury, Ph.D., Masood Machingal, Ph.D.

New tools help market technologies

Marketing technologies to industry is a key step in the commercialization process. Without active and strategic marketing, many technologies would remain hidden behind the walls of academia and unable to provide their intended benefits to society.

CTTC has implemented a number of strategies to aid marketing activities and increase the likelihood of technologies being licensed to commercial partners. These include a set of technology portfolios that highlight technologies in development at Vanderbilt, marketing videos that illustrate a technology's features and benefits, the integration of contacts in Salesforce, and attendance at industry conferences to pitch technologies to potential investors.

In recent months, CTTC has had a presence at the Southeast Medical Device Association annual meeting, the Licensing Executive Society of US and Canada conference, the Molecular Pathology Association annual meeting, BIO International Conference, and others.

What's on Deck

Healthcare Information Technology

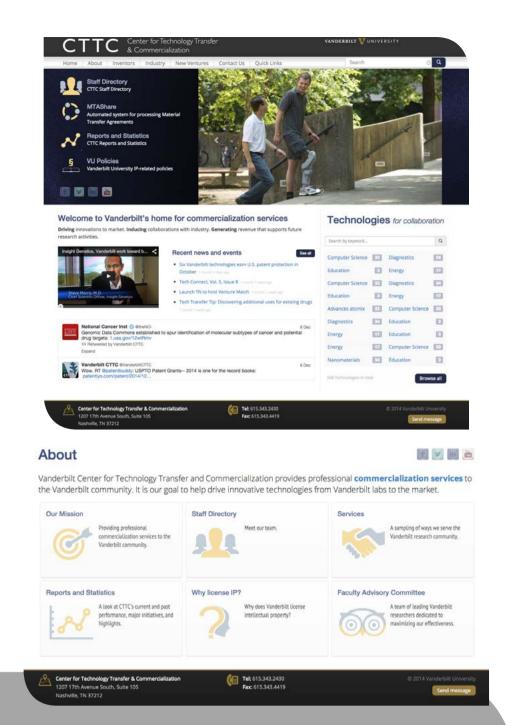
CTTC, in partnership with several research enterprises, has applied for a federal grant to support the development of healthcare information technologies. If awarded, the grant would support the building of a commercialization facility that would support R&D for new healthcare IT.

Database Updates

CTTC is moving to a new web-based database that will open the doors for a number of improved services to inventors, including an online invention disclosure system, an inventor portal for tracking the commercialization process, and more. These updates are expected to occur throughout 2015.

Website Makeover

Throughout the fall, CTTC has been redesigning its website. The new site is clean, easy-to-navigate, and packed with helpful information for Vanderbilt inventors, the entrepreneurial community, and industry partners curious about innovative R&D happening at Vanderbilt. The site will launch later in December. Until then, here is a sneak peak!





Have a question for CTTC?

Feel free to call our main office line at 615.343.2430

Visit us online at www.vanderbilt.edu/cttc







