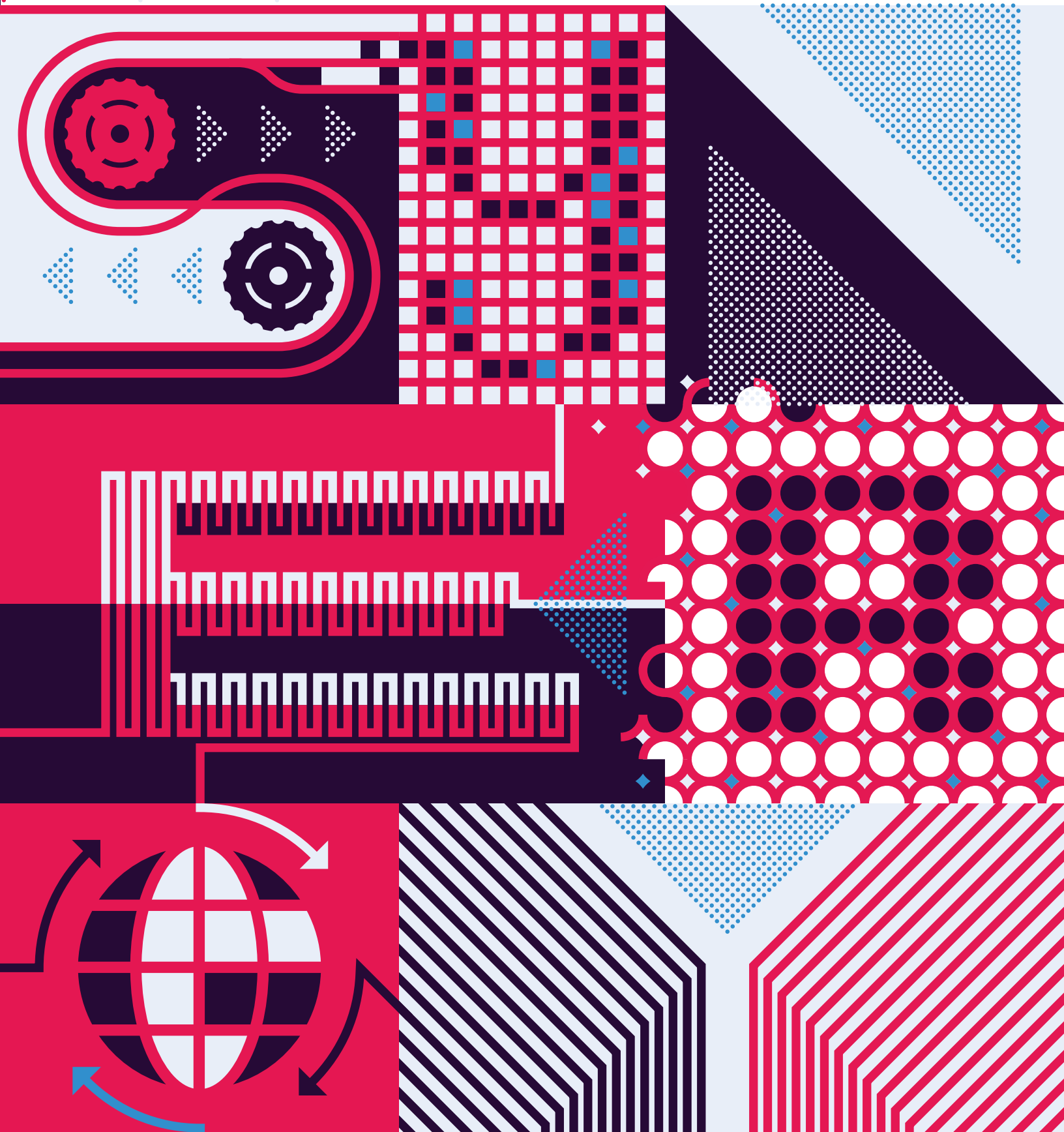
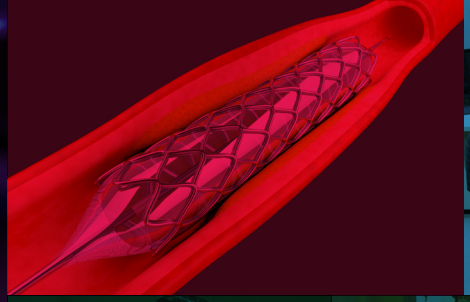
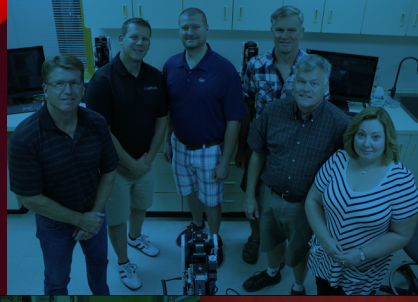
TECHNOLOGY & VENTURE COMMERCIALIZATION

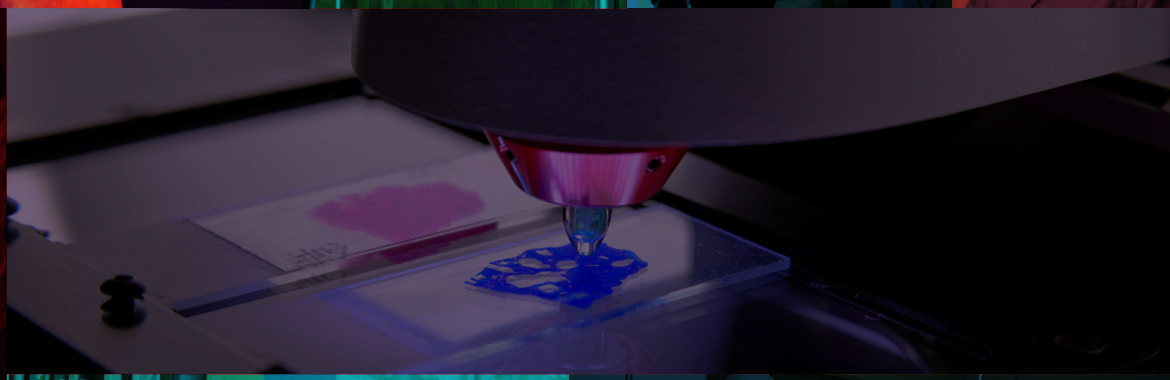
SYNERGY

ANNUAL REPORT 2016



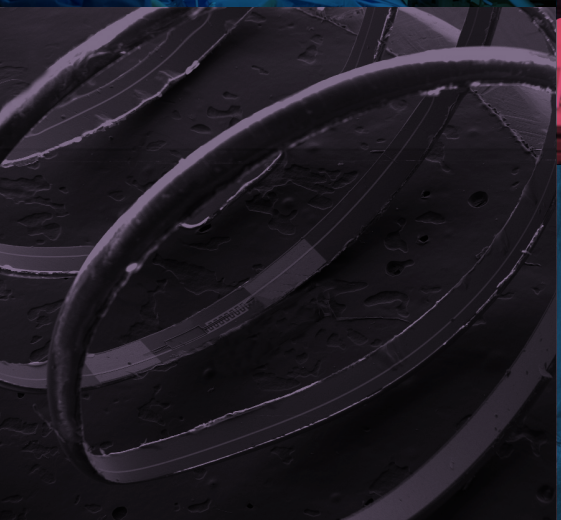





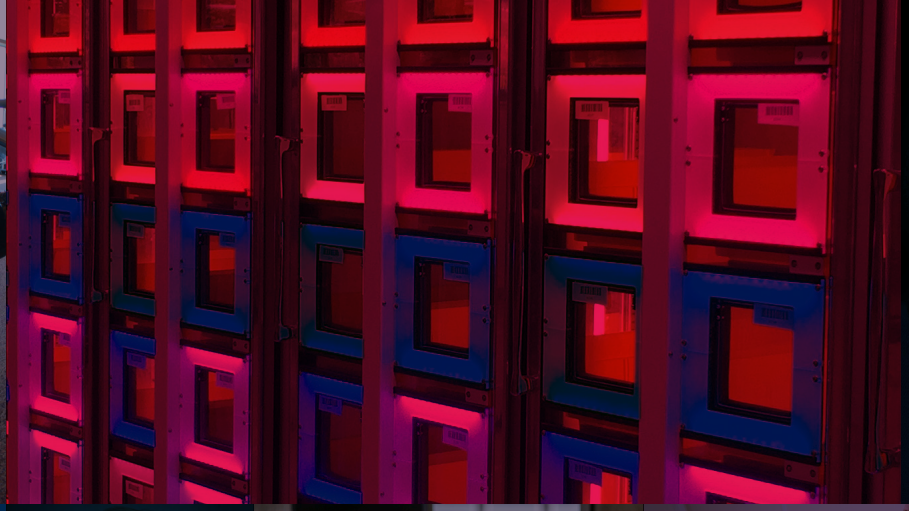


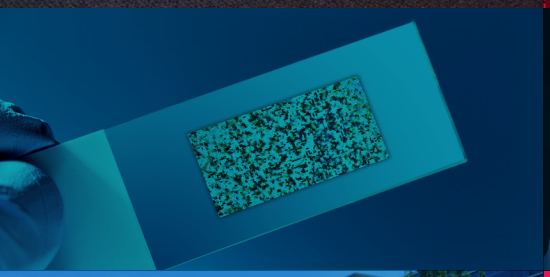





TECHNOLOGY & VENTURE COMMERCIALIZATION

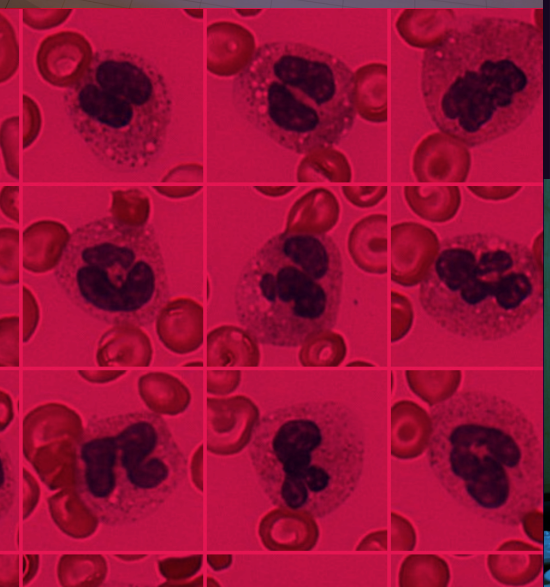
THE UNIVERSITY OF UTAH

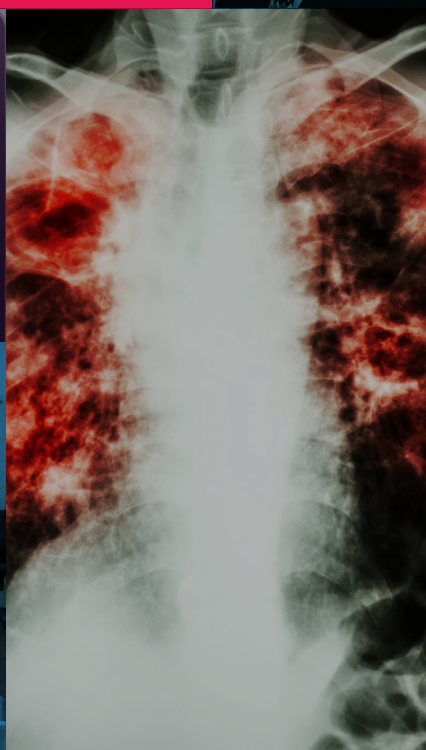







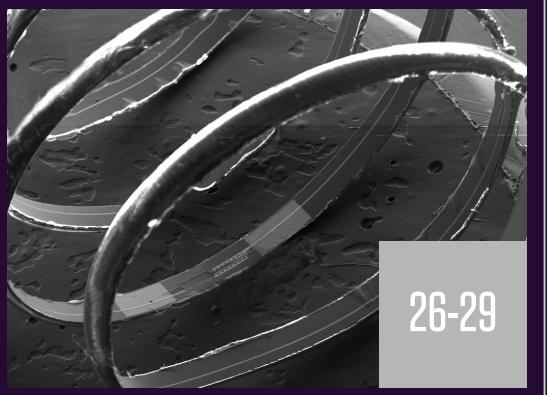




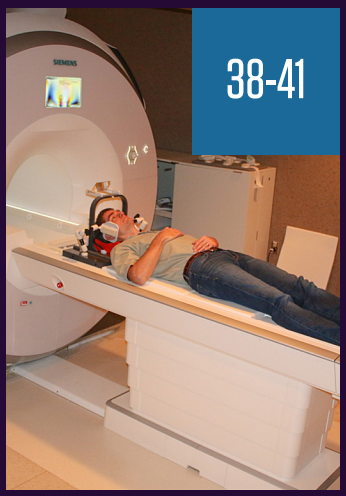
SYNERGY: WE BELIEVE THAT TECHNOLOGY COMMERCIALIZATION IS MOST SUCCESSFUL WHEN GROUPS AND INDIVIDUALS FROM DIVERSE BACKGROUNDS ARE ENGAGED TOGETHER IN THE PROCESS. EACH FILLS A UNIQUE BUT INTERCONNECTED NICHE THAT TOGETHER PRODUCES A TOTAL EFFECT ON COMMERCIALIZATION AT THE UNIVERSITY OF UTAH THAT IS GREATER THAN THE SUM OF THEIR INDIVIDUAL CONTRIBUTIONS.

CONTENTS



FEATURE 04

OUTSIDE EXPERTS REVITALIZE LOW BACK PAIN DEVICE



FEATURE 06

TVC'S LEAN CANVAS PROGRAM EMPOWERS DEVELOPERS TO IMPROVE EAR IMAGING

FEATURE 05

SEEDING SUCCESS WITH NEW MALE INFERTILITY TEST

FEATURE 07

MEDVIS SIMULATES BETTER DEVICE DEVELOPMENT

MESSAGE FROM THE INTERIM EXECUTIVE DIRECTOR

Successful Commercialization Requires A Community

Many experts believe that throughout recorded history collective human knowledge doubled approximately every 100 years up until around the year 1900. After this point, this doubling rate began to rapidly increase. It is now estimated that human knowledge doubles every 13 months, with the pace only continuing to quicken.[1]

This exponential growth in information has led to an explosion in new disciplines of study. According to the *Oxford Handbook of Interdisciplinarity*, there are now over 4,000 recognized academic specializations, with this number only continuing to grow.[2]

With this proliferation of scientific knowledge it is becoming ever more difficult for university technology transfer offices like Technology and Venture Commercialization (TVC) to efficiently evaluate, de-risk, and successfully commercialize the increasingly diverse inventions they receive by themselves. A few years ago, our office realized one of the most efficient ways to successfully manage this growth in multifarious discoveries was to create an evergreen network of external experts from as many fields of study as possible with whom we could rely upon to assist us in this exciting, yet diverse work. To help build such a network, we launched our Commercialization Engine Committee program in 2011.

The goal of the Commercialization Engine Committee is to receive advice and guidance on U technologies from individuals with experience in a diverse range of industries and disciplines. Members began making important contributions to the advancement of various U inventions not long after its formation. Because of this, and to intensify its impact, we made it an

office-wide priority to expand the committee's membership by 800 this year. I'm happy to report that we exceeded this goal. Nearly 900 external experts were added to the committee by the end of June.

Members of the Commercialization Engine Committee were also essential in TVC achieving its second office-wide goal this year: meeting 55 commercialization milestones. Achieving milestones adds considerable value to U technologies. Key value inflection points such as finding a problem/solution fit, creating a product development roadmap, engaging with qualified management, or securing funding move U technologies one step closer to commercialization. The 63 milestones various U technologies achieved this year simply could not have happened without the contributions and efforts of dozens of our Commercialization Engine Committee members. That is why for fiscal 2017 we plan to utilize this committee even more to achieve 74 milestones, nearly 20 more than the number we set for ourselves this year.

Key as it is, the Commercialization Engine Committee is only one of the many groups we are fortunate enough to work with. As one of the leading articles in this report makes clear, there are many innovative groups on campus that have been instrumental in the success of commercialization at the U. They are a major reason why this University has become so synonymous with entrepreneurism and innovation.

Each of these groups on campus, as well as the Commercialization Engine Committee, fill a unique but interconnected niche that together produces a total effect on commercialization that is greater than the sum of the individual contributions. This synergistic effect is why the U has been successful in the area of commercialization and is why with its recent surge, commercialization at the U faces a bright future.

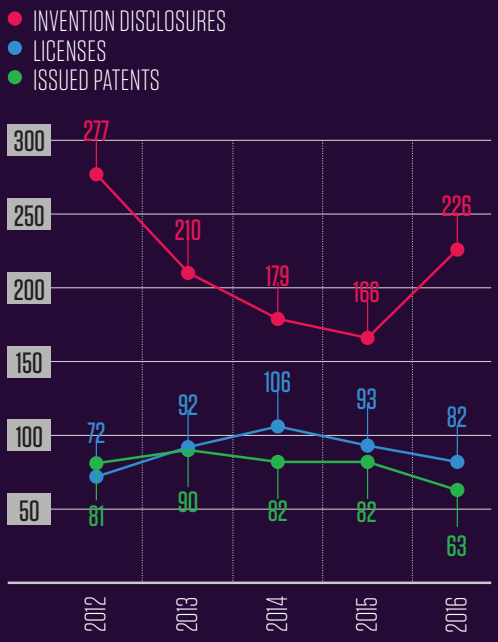
Finally, if you are a member of the Commercialization Engine Committee I would like to personally thank you for your support and assistance in helping TVC accomplish key commercialization milestones and evaluate hundreds of U innovations. THANK YOU! If you are not currently a member, I invite you to join. Come and be a part of this amazing work to help TVC and the U translate the exciting innovations developed at this great university and make an impact in our society.

Sincerely,

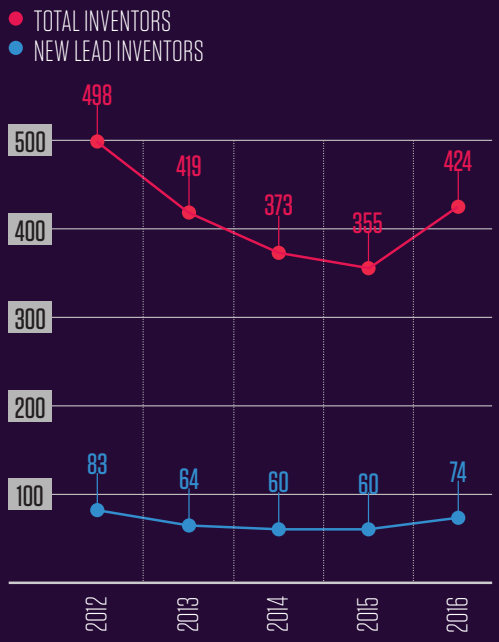
James E. Thompson
Interim Executive Director
TVC

2016 BY THE NUMBERS

DISCLOSURES, LICENSES & PATENTS

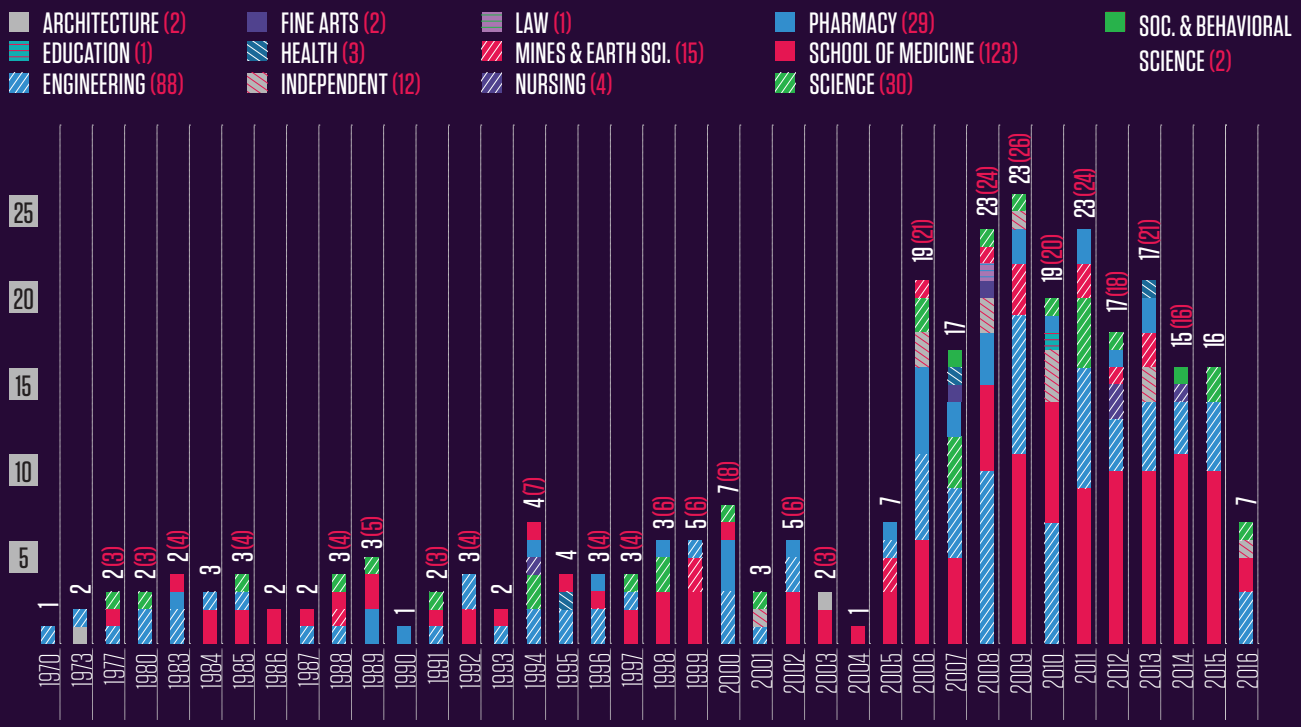


INVENTORS



SPINOUTS BY COLLEGE[1]

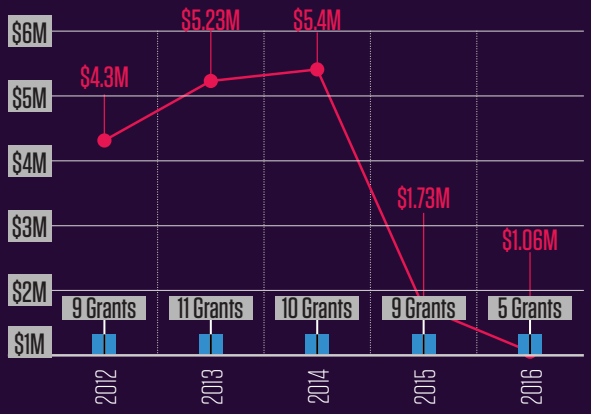
1970-2016



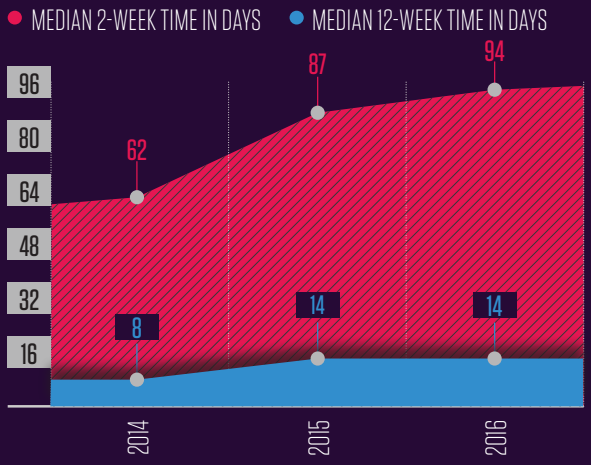
1. This chart lists the number of spinouts launched by year (the white-colored numbers above the colored bars) along with their college(s) of origin. The college of origin for each spinout was determined by the department(s) listed on the invention disclosure form by the principal investigator (PI) of each technology licensed to the spinout. Because many spinouts took licenses to multiple technologies, and because many of those technologies have different colleges of origin, the total number of spinouts is often lower than the total number of spinouts by college (the pink-colored numbers in parentheses) each year.

GOVERNMENT GRANTS

INCLUDES FEDERAL SBIR & STTR GRANTS SECURED FOR U SPINOUTS & TECHNOLOGIES

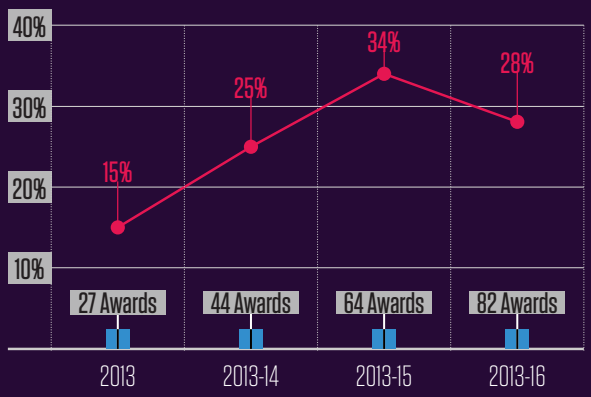


2-& 12-WEEK TVC RESPONSE TIME [2]



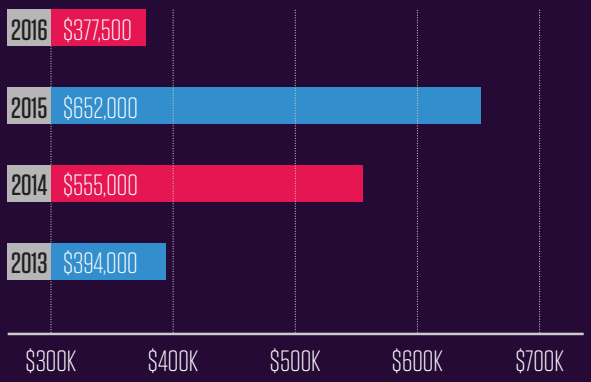
COMMERCIALIZATION ENGINE'S PERFORMANCE

% OF UNLICENSED ENGINE GRANT AWARDEES THAT WERE LICENSED AFTER AWARD



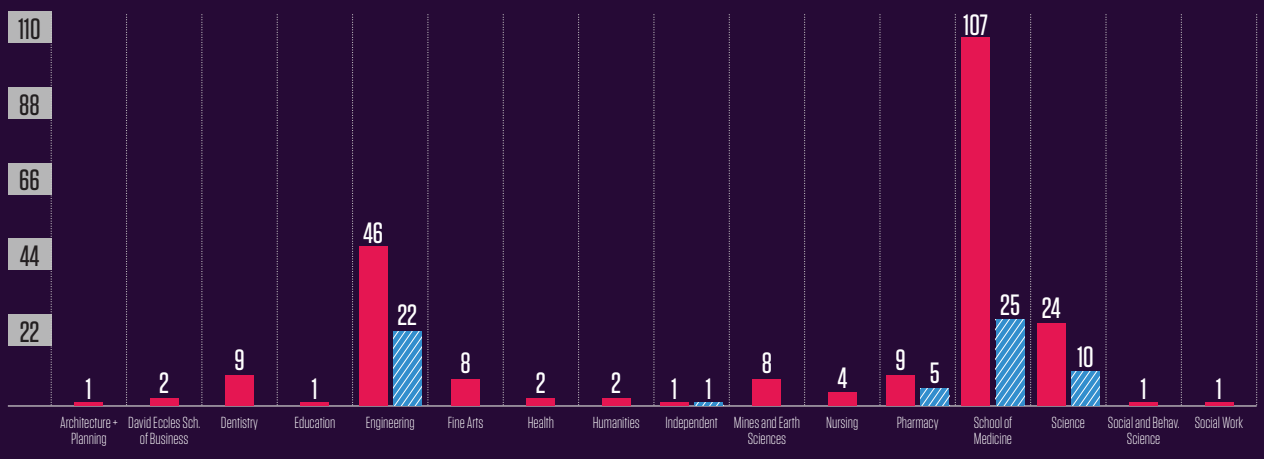
COMMERCIALIZATION ENGINE INVESTMENTS

TOTAL GRANT AMOUNTS GIVEN BY TVC TO U TECHNOLOGIES FOR DEVELOPMENT



2016 DISCLOSURES & PATENTS BY COLLEGE

INCLUDES THE COLLEGES OF THE PRINCIPAL INVESTIGATORS LISTED ON 2016'S INVENTION DISCLOSURES AND ISSUED PATENTS



2. TVC strives to meet with inventors within two weeks of invention disclosure to understand the disclosure and answer and ask questions. We then strive to meet with them again at 12 weeks (84 days) to discuss the path forward for their disclosed technology.

SPINOUTS LAUNCHED SINCE 1970

The U has been successful at creating spinout companies—especially in recent years. Below are spinouts by fiscal year with notation for status.

A Active I Inactive Q Acquired C Acquired but active with name at the time of acquisition

2016	
Blacksand Technology	A
Farhang Wireless	A
Fluidx Medical Technology	A
Frameshift Labs	A
iCORDS	A
ItRunsInMyFamily.com	A
Polarized Antenna Innovations	A
2015	
4DQC	A
6S Medical	A
Bastion Biologics	A
Clinacuity	A
IDbyDNA	A
Madra Learning	A
Majelco	A
NanoSynth Materials & Sensors	A
Origyn	A
ProMD	A
Safe Blade	A
Solefire	A
StreamDX	A
T3S Technologies	A
uBiota	A
Veritas Medical	A
2014	
ApopTx	A
Behavioral Health Strategies	A
Episona	A
Javali	A
Medvantage Corporation	A
NeuroCircuit Therapeutics	A
NeuroVersity	A
Orriant	A
Progenitor Life Sciences	A
Recursion Pharmaceuticals	A
Sentius Technologies	A
Symptom.ly	A
Tactical Haptics	A
Techcyte	A
Xenocor	A
2013	
Active Desk	A
Applied Biosensors	A
Arapeen Medical	A
ASHA Vision	A
CIRJ	A
Curza Global	A
Molecular Cloud	A
Navigen Endo-Shield	I
Ore to Metal Technologies	A
Proactive Memory Services	A
Resolution Applications	A
SimplicityMD Sharps	I
SimplicityMD Solutions	A
Synoptic	A
University Innovation Services	I
Verus Mobile Security	A
Vettore	A
2012	
Add-it	A
Creative Medical Health	A
DecipherGenX	I
Falgatter Technologies	A
iBiologics	A
Lazarus Medical	A
Lone Star Thiotherapies	A
MultiFunctional Imaging	A
Navillum Nanotechnologies	A
Pecten Technologies	I
PRONTO International	A
Salarius Pharmaceuticals	A
Utah Medical Solutions	A
Vaporsens	A
Veristride	A
Visus	A
Voyant Biotherapeutics	A
2011	A
AvanSci Bio	A
Axon Optics	A
Beijing Great Sun Biotech	I
CB Bioenergy	A
Cell Reader	I
CoNextions	A
Domain Surgical	A
e-Sens	A
Elute	A
Espira	A
Granite Mountain Technologies	A
HOT Water Global	I
Innoception Technologies	A
Knudra	A
MacCure	I
Perfect Vision	A
Seismic Option Safety Systems	I
SymbioCellTech	A
Telomere Diagnostics	A
TransViragen	A
US Bioremediation	I
Xandem	A
XEnd	A
2010	
7Revolutions	I
Brickell Biotech	A
Converus	A
F2 Solutions	A
Fay Financial Engineering	I
G6	I
iVeena Delivery Systems	A
Kayak Biosciences	I
KickStart	A
Predictive Medical	I
RedSpan	I
Salt Lake Biosciences	I
Seasonal Energy	I
Sfida Biologic	I
Short Solutions	I
Solan	A
Veritract	A
Versalion Pharmaceutics	I
Vutara	Q
2009	
Accendo	A
Blackrock Microsystems	A
Branching Tree	I
Energence	I
Ergonomic Tool Development	I
H2OTEQ	I
Headwaters Clean Carbon Serv.	I
Honde Environment	I
Integratech Proteomics	I
JSK Therapeutics	A
Marrek	A
Metallosensors	I
Miracotech	I
Nanomedic	A
Optema	I
Oscilla	I
Purple Energy	I
RNA Biosciences	I
Sci-U	I

- Sera Prognostics A
- TheraRenal I
- TheraTarget A
- Wastewater Compliance Systems A

2008

- Advanced Signal Detection I
- Akadi I
- Allegro Diagnostics Q
- BabyJock I
- BioEnergenix A
- Catheter Connections A
- Celux Scientific I
- Epitel A
- Geo Mind I
- GlycoMira Therapeutics A
- Heavystone Laboratories A
- I2S Engineering I
- Nano-Oxides A
- Nanonc A
- PFO Technologies Q
- Philotek I
- Rigalya Pharma I
- RU Ready A
- Surfagen I
- Trapeze Media Solutions I
- ViroPan A
- VisTrails A
- Wasatch Nanopore Sensors I

2007

- Bioclassifier A
- BioFuels Development Corp I
- Boulder Technology Devel. Labs I
- Central Logic A
- Clear Carbon Solutions I
- ContraDyn I
- Image Technologies A
- Larada A
- LV Partners Q
- Navigen A
- nFocus I
- Osteoseek I
- PowerMems I
- Polevault Media A
- RayScale Q
- Rescue Medical Systems A
- Thermimage I

2006

- AlloCure I
- Carbylan Biosurgery I
- Exeven V I
- Fuels Development Group I
- Glycosan Biosystems Q
- Heightened Technologies I
- Intan Technologies A
- Intellivis I
- LifeScan I
- LiveWire Innovation A
- Neuroadjuvants A
- Respiris Q
- SentrX Animal Care A
- TechnoImaging I
- Vestan Medical Imaging A
- Visual Share A
- Wasatch Microfluidics A
- Xapio I
- Zicthus I

2005

- Globalmatics I
- Goldfinger I
- Lineagen A
- MedAnalytics A
- Milcin Therapeutics I
- N-ERGY I
- Sentrx Surgical Q

2004

- Coherex Medical A

2003

- Applied Medical Visualizations A
- Q Therapeutics A

2002

- Amirsys A
- Hydra Biosciences I
- Versa Power Systems Q
- Visual Influence Q
- Wyoming Research Innovations I

2001

- Sensicore I
- Tramontane A
- Universe Partners I

2000

- Aciont A
- Allvivo Vascular A
- Attensity Corporation A
- ParSciTech I
- Pharmanex Q
- Salus Therapeutics (Genta) I
- Sonic Innovations I

1999

- Fiore Automation I
- MedQuest Products Q
- Mineral Technologies I
- TheraDoc I
- ThermaCom I

1998

- Echelon Biosciences A
- Spectrotek I
- Zars I

1997

- Cyberkinetics I
- Manticore Pharmaceuticals I
- Signature Immunologics Q

1996

- Cimarron Software C
- Rosetta Inpharmatics Q
- Viewpoint Manufacturing I

1995

- Diacor I
- ErgoWeb I
- Handtronix Corporation I
- Process Instruments A

1994

- BioCentrex I
- Cognetix I
- ENECO I
- Innovative Caregiving Resources I

1993

- HerediLab I
- PartNet C

1992

- Cardiowest Technologies I
- InfaBloc I
- Myriad Genetics A

1991

- BioFire Diagnostics (Idaho Tech.) C
- Femtoscan I

1990

- MicroMath I

1989

- MacroMed Q
- Parvus Corporation I
- TheraTech Q

1988

- Darbick Instructional Software I
- J. Bunger & Associates A
- Tepnel Lifecodes Q

1987

- A.D.A.M. Q
- Evans & Sutherland Q

1986

- Anesta Q
- NPS Pharmaceuticals Q

1985

- DataChem Lab I
- Rocky Mountain Research Q
- Techniscan Medical Systems I

1984

- ARUP A
- Engineering Geom. Systems Q
- Medtronic Gastro/Uro I

1983

- Datex-Ohmeda I
- Sarcos

1980

- Bunnel I
- Ceramatec A

1977

- FFFractionation Q
- Iomed Q

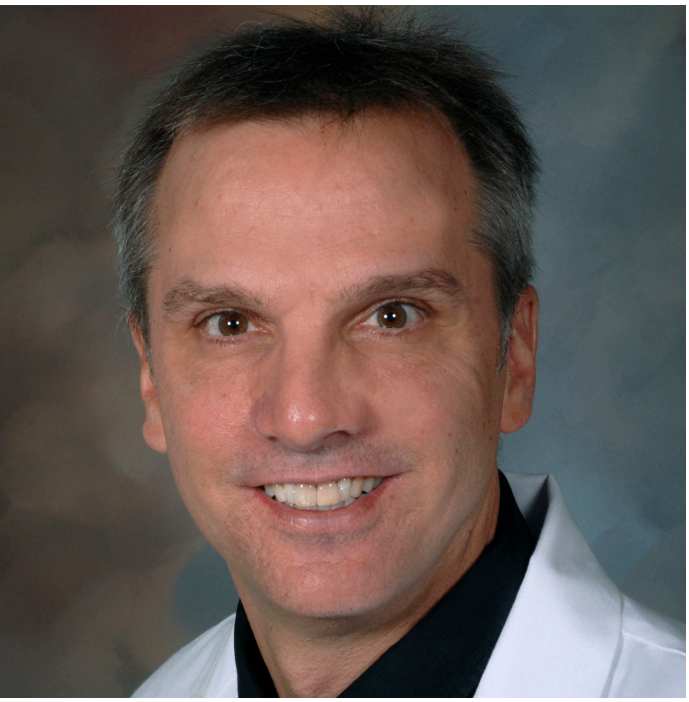
1973

- Advanced Composite Materials A
- Metals Manufacturing I

1970

- TerraTek Q

ANDREW WEYRICH NAMED THE U'S NEW VICE PRESIDENT FOR RESEARCH



Andrew Weyrich, the U's new vice president for research

Andrew Weyrich, most recently associate dean for research at the University of Utah School of Medicine, has been named the next vice president for research. He succeeds neurobiologist Tom Parks, who retired in June of this year after eight years as vice president.

"Dr. Weyrich understands what a research program needs to succeed, both as a physiologist and as an associate dean for research at the School of Medicine," says U President David W. Pershing. "His ability to coalesce teams to create collaboration and foster creativity will benefit this important area of the U's mission. I look forward to seeing the innovation that emerges under his leadership."

In his position at the School of Medicine, Weyrich helped develop and implement a strategic research plan and oversaw core facilities, recruitment, retention efforts, and graduate programs. As a professor of internal medicine, Weyrich holds an M. A. and the Edna Benning Presidential Endowed Chair, a recognition honoring the University's top medical researchers.

TVC reports directly to the Office of the Vice President for Research.

"The commercialization of our research discoveries at the University of Utah has had a tremendous impact on people's lives and on the common good," says Weyrich. "These positive effects are a principal reason why the University has so strongly supported its translational research. As the new vice president for research, I look forward to continuing this support and working with TVC to catalyze and transform our discoveries into practical use."

"THE COMMERCIALIZATION OF OUR RESEARCH DISCOVERIES AT THE UNIVERSITY OF UTAH HAS HAD A TREMENDOUS IMPACT ON PEOPLE'S LIVES AND ON THE COMMON GOOD. THESE POSITIVE EFFECTS ARE A PRINCIPAL REASON WHY THE UNIVERSITY HAS SO STRONGLY SUPPORTED ITS TRANSLATIONAL RESEARCH. AS THE NEW VICE PRESIDENT FOR RESEARCH, I LOOK FORWARD TO CONTINUING THIS SUPPORT AND WORKING WITH TVC TO CATALYZE AND TRANSFORM OUR DISCOVERIES INTO PRACTICAL USE."

—ANDREW WEYRICH, VICE PRESIDENT FOR RESEARCH

TVC LAUNCHES LEAN CANVAS PROGRAM

Matt Gardner, business development manager at TVC, leading a Lean Canvas discussion

Typical technology development models are good at explaining how a product goes from ideation to becoming a scalable product ready for the marketplace. Most of these models assume, however, that the technology being advanced will actually have customers who will purchase it when it becomes a product. In recent years, the National Science Foundation (NSF) has found that this assumption, particularly in academic research settings, is a big one to make. Simply put, a sizable number of inventions at universities are developed with little thought towards whether there will be customers willing to purchase what they have discovered.

The NSF founded its Innovation Corps (I-Corps™) program to help faculty take into account broader commercialization perspectives in their research. The NSF encourages select grantees to participate in its I-Corps™ Lean LaunchPad curriculum, which was developed by bestselling author and serial entrepreneur Steve Blank.

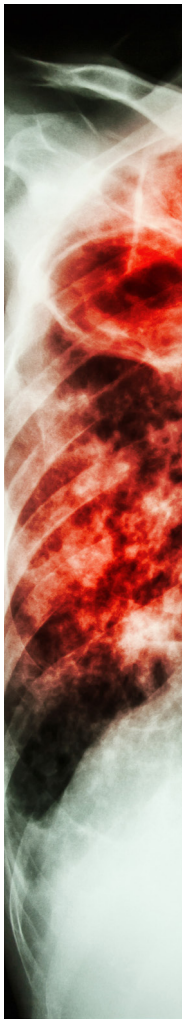
In early 2016, TVC created a customized version of the Lean LaunchPad for U technologies. Called the "Lean Canvas," TVC's curriculum, which is not under I-Corps™, draws heavily from Blank, but puts more of a focus on achieving business milestones than NSF's program does.

TVC's Lean Canvas program lasts seven weeks and is launched once a month. Teams are formed around each technology and are given a $4,500 drawdown budget. The goal for each invention is threefold. First, teams are to validate that the technology addresses an actual problem that real, potential customers are experiencing. Second, they are to validate that the technology solves that problem and that potential customers would purchase the product the team is developing. Third, they are to understand how large the market potential for their technology is. All of this validation requires that the teams conduct a sizable number of interviews with potential customers.

The story, "TVC's Lean Canvas Program Empowers Developers to Improve Ear Imaging" on page 38, documents a common occurrence in the Lean Canvas program: technologies making significant pivots to their core offerings based on the feedback they receive from potential customers. These changes, says Matt Gardner, business development manager at TVC, are making U technologies more valuable to potential licensees, entrepreneurs, and investors as they are aligning these discoveries more precisely to the market.

Technologies or U spinouts interested in being a part of TVC's Lean Canvas program should contact their business and technology development representative.

NANOSYNTH BEGINS TB FEASIBILITY STUDIES IN AFRICA AND ASIA



Although tuberculosis (TB) is now a relatively uncommon disease in North America and Europe, it still poses a major threat to many countries around the world. According to the World Health Organization, in 2014 alone, 9.6 million people fell ill with this disease and over 1.5 million died from it.[3] Effective and inexpensive drugs exist for most strains of TB but because it is usually slow in its progression and difficult to diagnose, it often goes undiagnosed, and thus untreated, in patients for many years. Coupled with the fact that it is highly contagious, the spread of TB can be difficult to control.

Jason Young of Nanosynth showing test results to Samir Pachpute of the MGM Institute of Health Sciences in Mumbai, India

Public health officials have known for decades that accurate diagnosis of TB is crucial for controlling its spread. Current diagnostic standards, however, can take weeks to confirm a clinical diagnosis, require highly skilled personnel and expensive specialized laboratory infrastructure, and suffer from either missing too many actual cases of the disease (false negatives) or identify too many people as having it when they really don't (false positives). Each of these limitations waste precious resources and allow the disease to spread. This often means that the areas that need proper diagnosis techniques the most go without them.

Realizing this, Swomitra Mohanty, assistant professor of chemical engineering, worked with Manoranjan Misra, professor of metallurgical engineering, to develop a technology that uses titanium dioxide nanotubes to detect TB. A nanotube is a hollow tube on the nanoscale (a scale operating at less than the width of a human hair) that can be made from a variety of materials. Misra and Mohanty were aware that active TB infections in the lungs

Colorized x-ray of a TB patient's lungs

Medical directors of various clinics around Mumbai, India meeting with Jason Young

give off four particular volatile biomarkers (chemical compounds that are a byproduct of the bacteria metabolism). They then realized that they could effectively measure the presence of these biomarkers by having an individual with TB breathe over an array of these nanotubes. As the infected individual's air passes through the array, the biomarkers bind to the nanotubes, resulting in a detectable electrical current that can be read by handheld electronic devices. This approach, which is very different from the current standard, enables the screening of patients for active TB on site.

The initial technology has been greatly refined since it was disclosed to TVC in 2011. It is now a robust, working prototype being commercialized by U-spinout Nanosynth Materials and Sensors. Individuals suspected to have TB only need to breathe one or two times into the device, compared to the standard method, which requires collecting a patient's sputum (a relatively difficult sample to collect, especially from children). Within 10 minutes the device will have an initial result as to whether or not the individual is suspected to have TB. If the result is positive, Nanosynth will recommend that that individual undergo confirmatory testing to establish the diagnosis and treatment if the patient is found to have TB.

Jason Young, CEO of Nanosynth, hopes to price the test in a similar range to that of a sputum microscopy or other screening tests. But because Nanosynth's test can be done on-site, has results ready in a fraction of the time compared to current standards, requires minimal training to run, and doesn't require a patient to cough up sputum, Young believes that adoption will be widespread.

Currently, Nanosynth is performing feasibility studies in India and Uganda. The first goal of these studies is to test how many false negatives and false positives the test produces. They are working towards a sensitivity of 90 percent for active pulmonary TB, which is significantly higher than current sputum microscopy tests. The second goal is to get usability feedback from both the operators of the device in India and Uganda as well as from the individuals it is being tested on. If the results of the feasibility study are positive, the company will begin raising funds for further development and clinical testing.

ARUP EMERGES AS A COMMERCIALIZATION LEADER AT THE U

A culture conducive to innovation and translational research has led to four promising U spinouts emerging from this lab in recent years

ARUP isn't just about processing your blood work. Innovation, research, collaboration, and commercialization have become an important part of this large laboratory's DNA. In the last five years alone, four promising U-spinout companies have emerged from ARUP initiatives and collaborations with groups on campus, and dozens of invention disclosures have come from its researchers, both faculty and staff.

SUPPORTING LABORATORY INNOVATION

Because ARUP is a nonprofit enterprise, it has certain obligations it must meet. While ARUP's for-profit competitors such as LabCorp and Quest Diagnostics distribute their profits to their shareholders each year, the money left over at ARUP after expenses must, by law, be reinvested back into the organization. According to Noriko Kusukawa, vice president and director of innovation and strategic investments at ARUP, the lab purposefully chooses to distribute a sizable portion of these reinvested funds to research and development. "We do this because one of our primary missions is to support the mission of the University of Utah," she explains. As a result of this focus, "...education, training, and research are very important to us."

According to Mark Astill, vice president of research and development at ARUP, this support results in approximately 150 peer-reviewed publications by ARUP faculty and staff each year. What sets this research apart from many other departments on campus, however, is that most of it is translational in nature. "ARUP's research and development has a small 'r' and a capital 'D'," Astill explains. "We don't do a lot of basic research here, important as it is. Rather, our focus is on developing pragmatic solutions to real-world problems."

This research focus on solving real-world issues lends itself to practical discoveries that are more easily commercialized than other types of research. As a result of this, ARUP set up an internal patent committee to routinely review inventions so they are vetted for real-life applicability and so that feedback from ARUP's industry partners can be sought early in the process. Kusukawa explains that when one of these inventions meets certain criteria, primarily when it is: relevant to what ARUP does, is likely to benefit the organization, and is patentable, the lab often chooses to support it further, both with funding of some sort as well as with commercial mentoring.

A PRAGMATIC APPROACH

ARUP's translational research focus arises for two reasons. First, because ARUP faculty and research staff are heavily

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involved in the many tests performed at the laboratory, they are often interested in finding ways of making them more efficient. Second, because many of the faculty routinely work with clinicians to manage patients, or in some cases see patients themselves, they have a strong interest in bettering patient care. These two foci have led directly to four U spinouts emerging in recent years from ARUP research, each determined to both improve laboratory science and provide better patient care.

4DQC

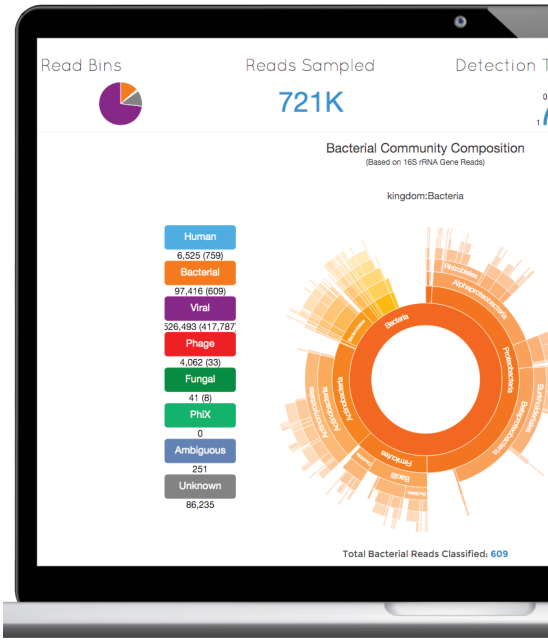
4DQC (Fourth Dimensional Quality Control) is a recent U-spinout based on the efforts of Frederick Strathmann, assistant professor of pathology. Strathmann has designed software that is focused on laboratory-wide data capture and real time metric presentation in a dashboard format, sort of a DOMO for the laboratory science world. Routine tasks that medical technologists perform when troubleshooting issues are also automated by the software, thus allowing lab managers to see potential problems before they arise.

The goal of 4DQC is to lead a change from retrospective data review processes that dominate current laboratory quality assessments to real time, prospective analyses that use automated quality metrics and predictive analytics. This, Strathamnn believes, should result in less "do over" tests for patients and more tests being able to be run on existing equipment each day. The company is currently planning a soft launch of its software within ARUP this fall.

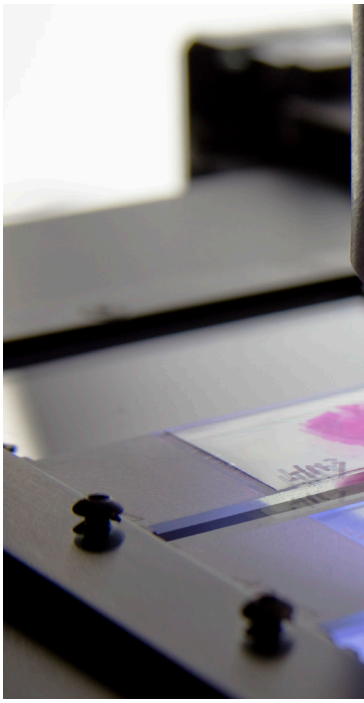
TECHCYTE

Like 4DQC, U-spinout Techcyte also seeks to improve current laboratory methods.

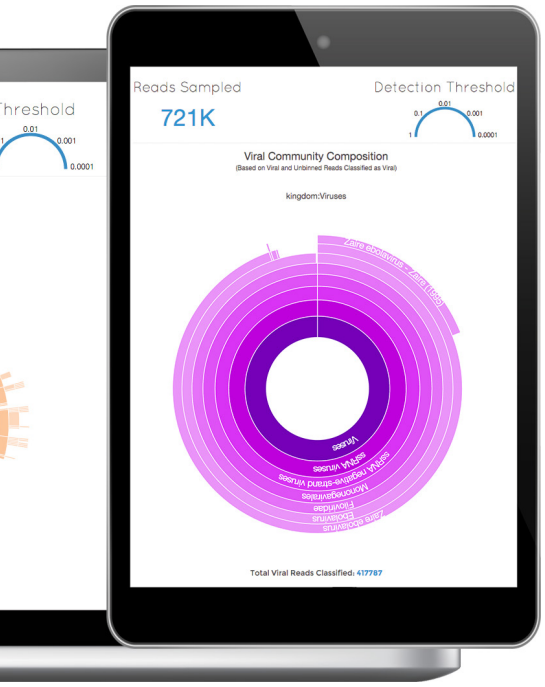
Screenshot from Taxonomer

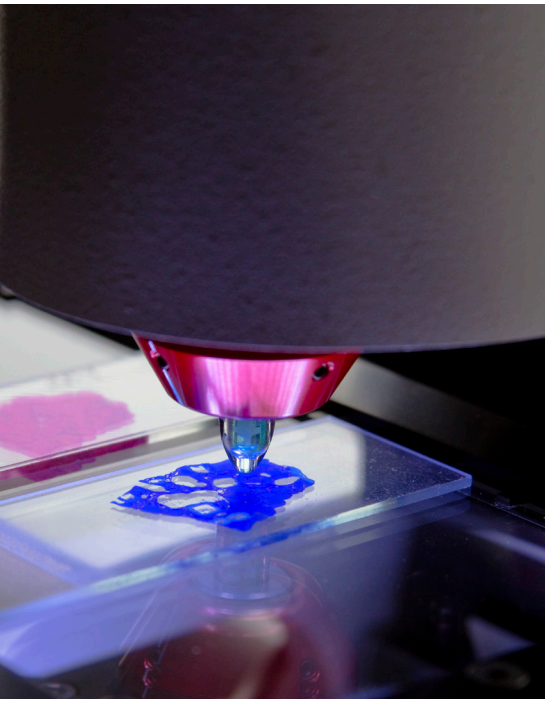


Frederick Strathmann, assistant professor of pathology and inventor of 4DQC's technology



AvanSci Bio's MilliSect™ Instrument





Mohamed Salama, professor of pathology and co-inventor of Techcyte's technology

Each day, millions of common tests such as a complete blood count or a urine test are ordered by physicians and processed by advanced machines. These machines are programmed to flag samples that deviate from a normal range. Flagged tests often require further examination. When this is the case, a small portion of the sample being tested is smeared onto a slide (e.g., blood, urine, feces, etc.) and sent to a pathologist to review under a microscope. These pathologists must manually count cell types to either confirm the machine's findings or contradict them. If, for example, a blood test has revealed that a patient has an abnormally high white blood cell count, the pathologist must manually count the number and types of white blood cells on that sample. "This manual process is tedious for pathologists," explains Mohamed Salama, professor of pathology and a co-inventor behind Techcyte's technology.

Believing that there must be a way to utilize technology to do this type of counting for pathologists faster and better, Salama decided to team up with Tolga Tasdizen, an associate professor of electrical and computer engineering at the SCI Institute, along with one of Tasdizen's students. Together, the team created software that automatically classifies the contents of slides using advanced deep learning algorithms. When the software is launched, all Techcyte's clients will need to do is log on to Techcyte's website and digitize a slide by scanning it under a microscope scanner. The slide will then be automatically uploaded to Techcyte's servers where its contents will be rapidly pre-classified and identified. One of Techcyte's major goals is to provide a tool that supports pathologists and laboratory professionals with work flow efficiency.

According to Ralph Yarro, the company's CEO,

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Techcyte will be launching a minimum viable product (MVP) of its offerings in October of this year.

IDBYDNA

Although diagnostic tests have become far more effective and technologically advanced in recent years, many of these tests are limited by the fact that they are designed to check for a small number of diseases. When faced with the presence of a possible infectious disease such as malaria or tuberculosis, physicians must check a patient's symptoms, match those symptoms to a known infectious disease, and then run a test for it. If that test comes up negative, they must run a test for another disease, and so on until the source of the infection is found.

Robert Schlaberg, assistant professor of pathology and co-inventor of IDbyDNA's technology

Taking advantage of recent gains in next generation sequencing (processes that sequence DNA and RNA much more quickly and cheaply than previously done) and big data (the ability to quickly process large amounts of complex information), a team of researchers at the U have developed a revolutionary new software tool that rapidly reads DNA and RNA sequences from biological samples, and determines which infectious agents are present in a patient's bodily fluids. This software tool, called Taxonomer, is the core technology behind U-spinout IDbyDNA. It was developed by a large multidisciplinary team from ARUP, Human Genetics, the USTAR Center for Genetic Discovery, Biomedical Informatics, Pediatric Infectious Diseases, and representatives from the Centers for Disease Control and Prevention (CDC). According to Mark Yandell, co-inventor and professor of human genetics, "Taxonomer can detect known and even unexpected pathogens in patient samples all at once."

Taxonomer will also be useful in diagnosing the exact type of pathogen that has caused a patient's disease. "Pneumonia, sepsis, and encephalitis can all be caused by a very large number of pathogens," explains co-inventor Robert Schlaberg, assistant professor of pathology. "Identifying the pathogen responsible will enable physicians to target them with the appropriate treatment."

Schlaberg says that the company is preparing for launch of a Taxonomer-based diagnostic test in collaboration with ARUP in the fall of 2016. Taxonomer is available at *www.taxonomer.com*.

AVANSCI BIO

The recent growth in genomic testing of tumors over the last 10 years is allowing doctors to determine which gene mutations are involved in a patient's cancer and which are not. Such information is important because some gene mutations are more likely to respond to a particular drug than others. This type of testing is one of the primary reasons behind the growth of personalized cancer treatment plans that oncologists are preparing for their patients more frequently. However, nearly all of these tests, known as molecular tumor tests, require that specific cells of interest be dissected out from a

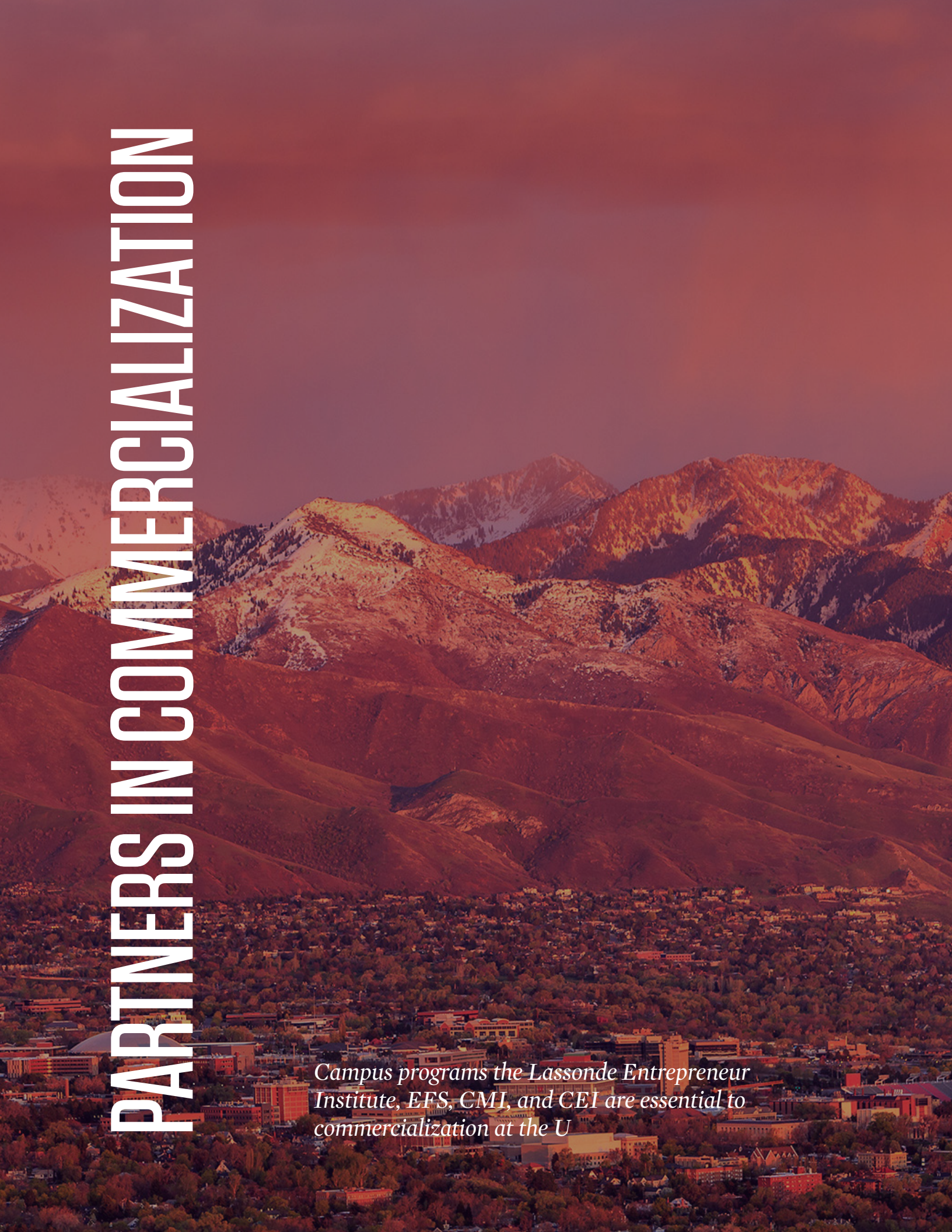
patient's tissue sample (usually cancerous tumor cells). Such samples, or biopsies, are far more invasive to collect from patients than simple procedures such as blood tests. Some biopsies require surgery, and nearly all require some kind of anesthesia be used. Understanding this, Katherine Geiersbach, former assistant professor of pathology at the U, was always frustrated when she had to request a new biopsy be done on a patient because the cancerous tissue content on the original biopsy sample was too small for a molecular test to be run. She soon realized, however, that the issue wasn't the samples; it was in how the cancerous content is collected for analysis. Most tissue for molecular tests is acquired by hand using a scalpel. This method sometimes doesn't allow a pathologist to precisely collect enough pure sample for molecular testing, particularly when the amount of tissue is small to begin with. A laser method also exists to collect precision samples, but these instruments can cost up to $500,000 and can be difficult to use.

Geiersbach knew that there had to be a more precise yet cost-effective method for precisely extracting pure amounts of cancerous tissue from biopsies. When outside technology developers Nils Adey and Rob Parry of Salt Lake City-based AvanSci Bio heard about this issue from Geiersbach, they decided to team up with her, Mark Herrmann, who was with ARUP at the time, and the Software Development Center at the U to solve it. The result was a tool called the MilliSect™ Instrument that was initially sold by the U-spinout. This technology, now owned by Roche Diagnostics, is able to extract tissue samples as small as 250 microns across (a human hair is about 75 microns across by comparison), far more precise than hand scraping samples produce. MilliSect is also automated, computer-controlled, hands-free, and much less expensive than laser methods. It is saving pathologists time and, more importantly, resulting in less patient biopsies having to be redone.

SYNERGIZING WITH THE U

Astill is quick to point out that none of the U spinouts that have emerged from ARUP research could have happened if it wasn't for the alliances it has developed with other groups on campus. "Because laboratory medicine covers so many different fields, it is essential that we forge strong partnerships with colleagues across campus to effectively do and translate our research," he explains. 4DQC, for instance, worked with the U's Software Development Center (SDC) and a student team from the Lassonde New Venture Development Center, Techcyte teamed up with colleagues from the SCI Institute to produce its software program, inventors from multiple departments formed IDbyDNA, and AvanSci Bio's instrument required the expertise of the U's SDC as well as outside experts. This synergistic effect has led ARUP to become both a leader in laboratory science as well as in technology commercialization.

The AvanSci Bio Team (left to right): Rob Parry, Derek Bosh, Mike Worthen, Nils Adey, Dale Emery, and Shelly Kaufman



PARTNERS IN COMMERCIALIZATION

Campus programs the Lassonde Entrepreneur Institute, EFS, CMI, and CEI are essential to commercialization at the U

The accomplishments the U has enjoyed over the past few decades in the area of technology commercialization have not been accidental. One of the primary reasons for this success has been due to the unique spirit of collaboration and impact that pervades this campus. As Vivian Lee, CEO of University of Utah Health Care, has put it, "Our ecology breaks down silos, spawns collaboration, and organizes innovation around its most central core for success: great ideas." Whether as a direct result of this spirit of collaboration or as a driver behind it, many interdisciplinary groups have emerged as key players in the commercialization process on campus. The Lassonde Entrepreneur Institute, the Entrepreneurial Faculty Scholars (EFS), the Center for Medical Innovation (CMI), and the Center for Engineering Innovation (CEI) are each a key source of new discoveries on campus, as well as crucial drivers of their development. Each fills a unique but interconnected niche that together produces a total effect on commercialization at the U that is greater than the sum of their individual contributions.

LASSONDE ENTREPRENEUR INSTITUTE

The Lassonde Entrepreneur Institute is a nationally ranked center within the David Eccles School of Business that focuses on student entrepreneurship and innovation. It was the first program at the U to emphasize these disciplines and is largely viewed as the catalyst from which the highly successful innovation and entrepreneurship movement at the U emerged. It started as a single project in 2001 following a donation from successful entrepreneur, gold investor, and U alumnus, Pierre Lassonde. This initial program, called the Lassonde New Venture Development Center, focuses on helping graduate students from nearly all majors and backgrounds commercialize faculty inventions. The Lassonde Entrepreneur Institute has since grown tremendously to include more than 20 additional programs as well as a new $45 million dollar building on campus called Lassonde Studios, where 416 students live with other entrepreneurial-minded students to create and launch new companies.

The Lassonde New Venture Development Center has had a significant impact on commercialization at the U. Prior to Lassonde's involvement with faculty inventions in 2001, TVC (then the Technology Transfer Office) was, like nearly all other technology transfer operations at the time, focused on simply handing off the intellectual property emerging from the U's labs to existing companies with little internal development taking place. The New Venture Development Center's focus on de-risking technologies, doing in-depth

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market evaluations, researching competitors, developing business models, and determining funding strategies for U technologies was groundbreaking for its time, and is largely the basis from which the Commercialization Engine Program that TVC launched in 2011 emerged.

Some of the first projects New Venture Development Center students worked on were inventions from Glenn Prestwich, Presidential Professor of Medicinal Chemistry and Special Presidential Assistant for Faculty Entrepreneurism at the U. Some of the first projects New Venture Development Center students worked on were inventions from Glenn Prestwich, Presidential Professor of Medicinal Chemistry and Special Presidential Assistant for Faculty Entrepreneurism at the U. These resulted in three successful U-spinout companies: Carbylan Biosurgery, Sentrx Animal Care, and Glycosan Biosystems, each of which came from a separate field of use being recognized for the technologies behind previously founded U-spinout Sentrx Surgical, a regenerative medicine company with licenses to some of Prestwich's inventions. According to Troy D'Ambrosio, executive director of Lassonde, "this early success got the attention of many faculty members on campus and raised our profile." Within a few short years, the New Venture Development Center had more projects than its teams could work on.

Altogether, New Venture Development Center students have helped over 250 faculty inventions as well as 48 of the U's spinouts, including being instrumental in the success of Lineagen, Navillum, and Veritract among many others.
Currently, New Venture Development Center students work on faculty inventions that TVC has questions about or

Lassonde New Venture Development Center students

Dale Clayton, professor of biology, making a point at an EFS event

James L. Sorenson Molecular Biotechnology Building, home of CEI

Glenn Prestwich, founder of EFS, Presidential Professor of Medicinal Chemistry, and Special Presidential Assistant for Faculty Entrepreneurism at the U

needs more information on. "We have the ability to do in-depth dives of technologies for TVC for six months or a year that they simply do not have the luxury of doing," explains D'Ambrosio. "TVC has to deal with volume and does not have the resources to devote the time and manpower to the invention disclosures they assign us that we can."

ENTREPRENEURIAL FACULTY SCHOLARS (EFS)

Glenn Prestwich launched EFS in 2007. Originally the Entrepreneurial Faculty Advisors, EFS was the first faculty entrepreneur group ever established in an academic setting, with a focus on mentoring and networking to facilitate the commercialization of faculty inventions. Seasoned faculty with extensive experience in commercialization help innovative faculty who are just starting down this path to understand and navigate the often perilous translational and commercialization waters. The EFS also encourages faculty to act as mentors to their entrepreneurial-minded students, a group Prestwich believes is essential for creating a sustainable "culture of impact" on campus. The EFS also hosts and participates in multiple networking, innovation, translational medicine, and transdisciplinary research programs throughout the year.

The EFS has had a very tangible long-term effect on commercialization at the U. Its programs have greatly improved the communication between faculty and TVC, which has in turn increased disclosures, patents, company startups, and the success of U-spinouts. The EFS also established the Distinguished Innovation and Impact Award, presented annually at graduation to faculty whose innovations have had significant impacts on people's lives. Moreover, the EFS has established innovation and impact as a priority for faculty retention, promotion, tenure, and for

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transforming the student experience at the U.

CENTER FOR MEDICAL INNOVATION (CMI)

According to John Langell, executive director of CMI and assistant professor of surgery, "physicians and nurses see the real pain points in medicine. They know what needs to be fixed. They generally don't, however, have the necessary engineering, business, or law experience to actually fix these problems. As such, many pain points in medicine often go unaddressed." Determined to correct this, Langell—together with colleagues from Bioengineering, Business, and Law—formed CMI in 2012. Its goal is to help faculty and students conceptualize, materialize, and commercialize inventions that address market needs in the medical space by bringing people together from multiple disciplines. It does this by offering a number of educational programs such as BioInnovate and Bioimmersion; providing in-house services such as advanced prototyping, regulatory compliance aid, simulations, and patent filing; partnering with over 65 companies and investors outside of the U; mentoring, by giving inventors access to over 100 experienced advisers; and through cash-award competitions such as Bench-to-Bedside.

John Langell, director of CMI, addressing the audience at a Bench-to-Bedside event

CMI had originally planned to accelerate mostly faculty inventions but they soon realized that most of the drive for innovation was coming from pure student-driven intellectual property. A certain percentage of faculty in Health Sciences have found it more advantageous for them to simply report a pain point that they have identified and then let CMI address it rather than to create a solution themselves. CMI compiles a list of these pain points and allows the multidisciplinary teams of graduate and post-doctoral students in the BioInnovate program to choose the one that is most interesting to them, or to address a pain point of their own choosing. These teams are then given the resources and education to solve that problem by taking it from concept to reality.

In the four short years since its launch, CMI has seen remarkable success. 37 companies have been launched from its programs and over $5.5 million dollars in investment funds have been raised for these companies. Two of these spinouts, Veritas Medical and StreamDx, are likely headed for particularly bright futures. Veritas, a pure student intellectual property company that emerged from the BioInnovate program, has won numerous awards including this year's Utah Innovation Awards in the medical devices category, and has won multiple business plan competitions as well. Their Light Line™ catheter uses a unique kind of light to kill bacteria to prevent the occurrence of catheter-caused infections. StreamDx had its beginnings with CMI a few years ago when Jim Hotaling, assistant professor of urology, provided a BioInnovate team with a problem relating to Lower Urinary Tract Symptoms (LUTS) in men. The company, which is rapidly approaching commercialization, now

has an advanced prototype that will allow accurate measurements of urinary stream flow be done at home, something not currently available.

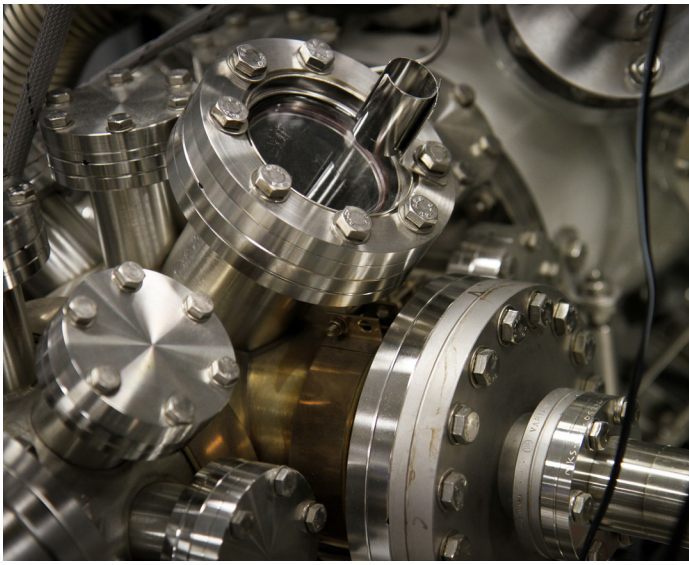
CENTER FOR ENGINEERING INNOVATION (CEI)

At the U, disclosing an invention to TVC is almost always the first in a long series of steps that must occur in order for that discovery to reach the market. A significant portion of the inventions that TVC receives must meet important technological and scaling milestones before they can be commercialized. Due to their highly technical nature, it can often be difficult for U technologies to find a partner sophisticated and specialized enough to help them achieve these milestones, especially in the field of engineering. With a large number of both U and non-U engineering technologies having difficulty finding such a partner, CEI was launched in 2013 to address this need.

CEI provides highly specialized, fee-based engineering services to faculty researchers, businesses, entrepreneurs, and inventors. It offers prototype development, general contract engineering and research services, in-vitro and in-vivo pre-clinical medical device testing, and micro and nanotechnology development. According to Florian Solzbacher, CEI's director, no other publicly accessible facility in Utah can provide the number of capabilities, density of unique and complex tools, and access to a deep reservoir of knowledge in highly advanced technologies and their respective application fields and markets than CEI can.

CEI is also in the matchmaking business. It leverages its relationships with many of the other centers and labs on campus to establish collaborations and partnerships for its clients when a multidisciplinary approach is required.

From 2013-2015 CEI participated in 41 research partnerships and interacted with 13 U departments and 42 companies on 92 projects, including a number of U engineering technologies. Most recently, Applied Biosensors, a U-spinout that makes an inexpensive, disposable single-use sensor that can monitor multiple substances without the risk of contamination, had its technology accelerated and validated by CEI.

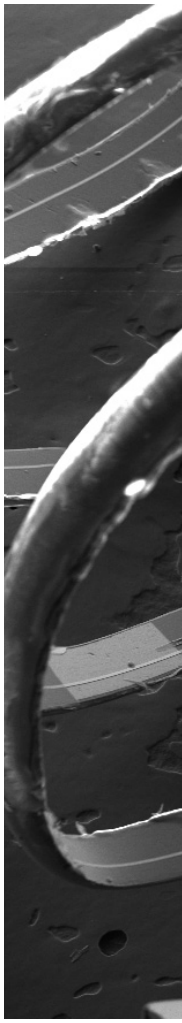


Equipment in one of CEI's labs

CONCLUSION

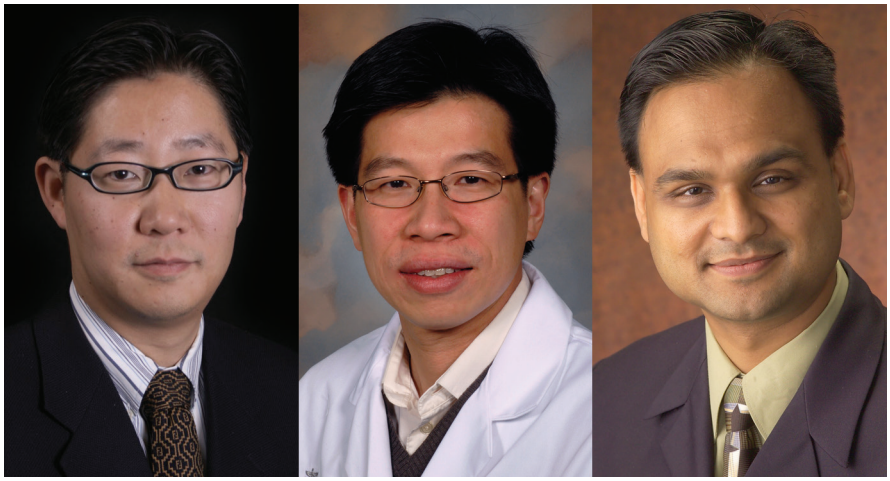
Commercialization at universities will require an integrative approach to succeed in the future. TVC has been fortunate to benefit from a campus where such an approach happened organically. With the Lassonde Entrepreneur Institute, EFS, CMI, and CEI each working to promote innovation and commercialization in their own respective niches, they have helped to create a commercialization enterprise at the U that simply could not have been established by TVC alone. With the continued growth of each of these programs, commercialization at the U will almost certainly be enriched even more.

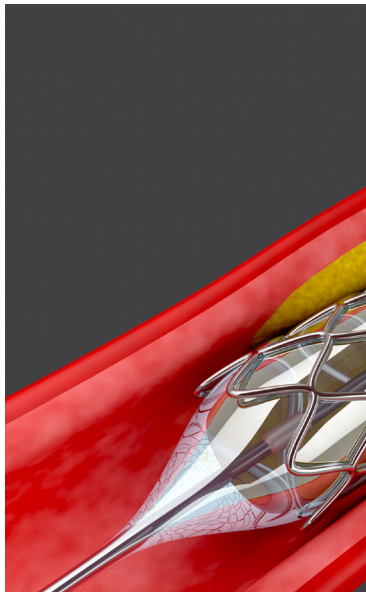
CATCHING ARTERY STENT FAILURES BEFORE THEY HAPPEN



More than half a million Americans are diagnosed with heart disease on an annual basis,[4] adding to the already 27.5 million Americans who currently live with it.[5] Each year, some of the arteries of approximately 600,000 of these individuals become so clogged with plaque (cholesterol, fat, calcium, and other substances), they have to undergo a procedure known as a percutaneous coronary intervention (PCI), or angioplasty with stent, to unblock them.[6] In this procedure, a cardiologist inserts a catheter into the patient's affected artery. Its movements through the artery are monitored by the use of live x-rays. When the catheter reaches the location of blockage, the cardiologist inflates a tiny balloon on the catheter's tip. This action widens the artery by compressing the buildup of plaque and

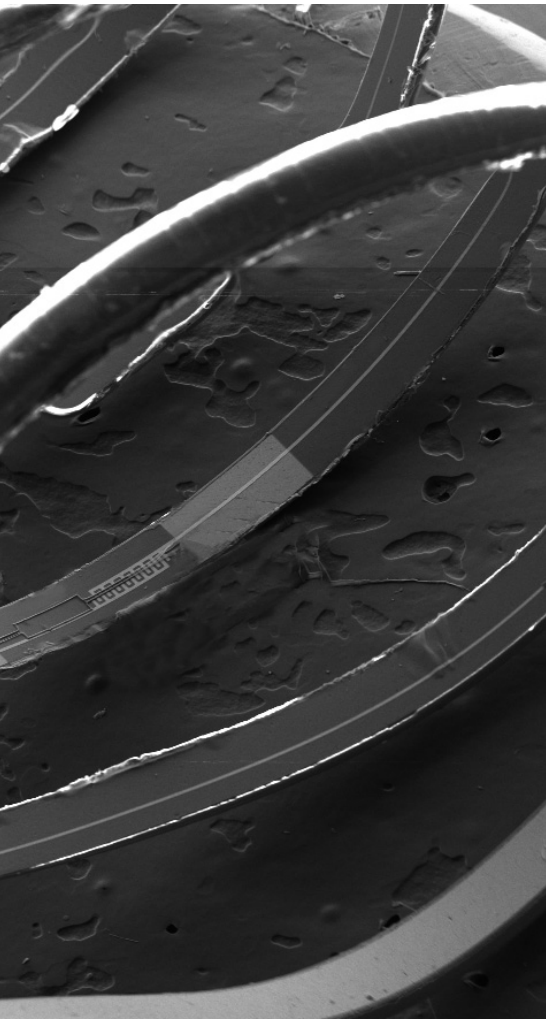
Inventors (left to right): Hanseup Kim, Anwar Tandar, and Amit Patel

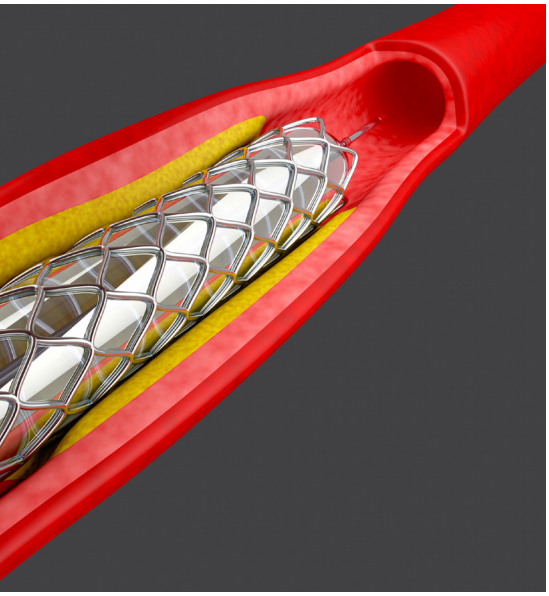




Cardiac catheterization procedure

Kim, Tandar, and Patel's stent under a microscope





A 3D rendering of a stent

restores proper blood flow. As the balloon inflates, a small wire mesh tube known as a stent expands with it. The stent locks into place and is left behind in the artery to help keep blood flowing freely.

The goal of a PCI is to prevent restenosis, or the re-blocking of the stented artery with a new buildup of plaque, as well as clotting, or stent thrombosis. Despite recent advances in stents, restenosis still occurs in up to 40 percent of cases, and often within months.[7] Because of this, patients must be routinely checked. Current methods of monitoring, however, are based entirely on clinical symptoms such as chest pains or shortness of breath.

The most commonly used techniques available for restenosis monitoring are difficult on patients. "Cardiac catheterizations are too invasive to be done annually, even though this is the standard of care" explains Amit Patel, professor of surgery at the U. "And coronary CT scans of the heart involve radiation, which can damage DNA and cause cancer with repeated use, and contrast, which can damage the kidneys over time." Another monitoring method, stress tests, requires patients to either exercise on a treadmill or receive medicine that causes their heart rate to increase. Pictures of the heart are taken before the increase in heart rate begins and when it reaches certain peak levels. This test, explains Anwar Tandar, assistant professor of internal medicine at the U, is "not 100 percent accurate and can be cumbersome."

Patel goes on to explain that the invasiveness of these monitoring methods is only one problem with the current approach. The other, and perhaps more important issue with current methods, is that they are not proactive. "You don't know when a stent is going to fail," Patel explains. "There's no way to predict re-blockage of an artery beforehand."

Routinely faced with these problems in their patients, Patel and Tandar, who often work together, decided that a non-invasive method that catches the beginning stages of restenosis and clotting in stented arteries before symptoms develop was needed. In 2012, Tandar came up with a basic idea for a device,

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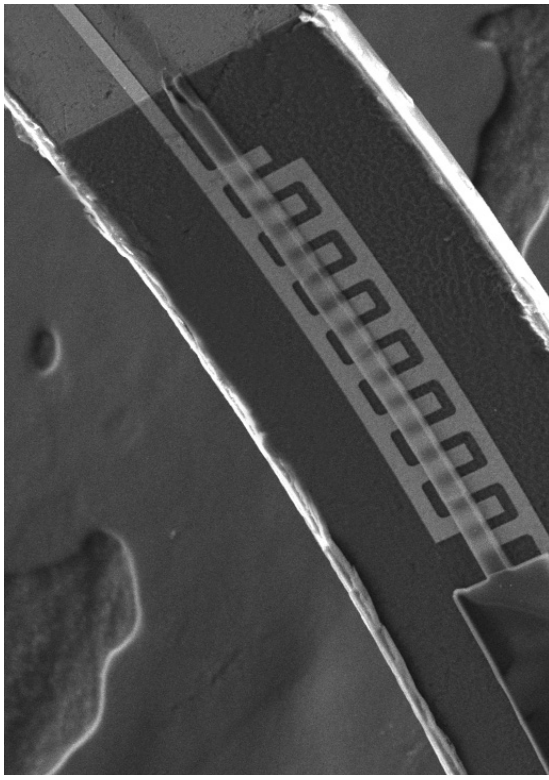
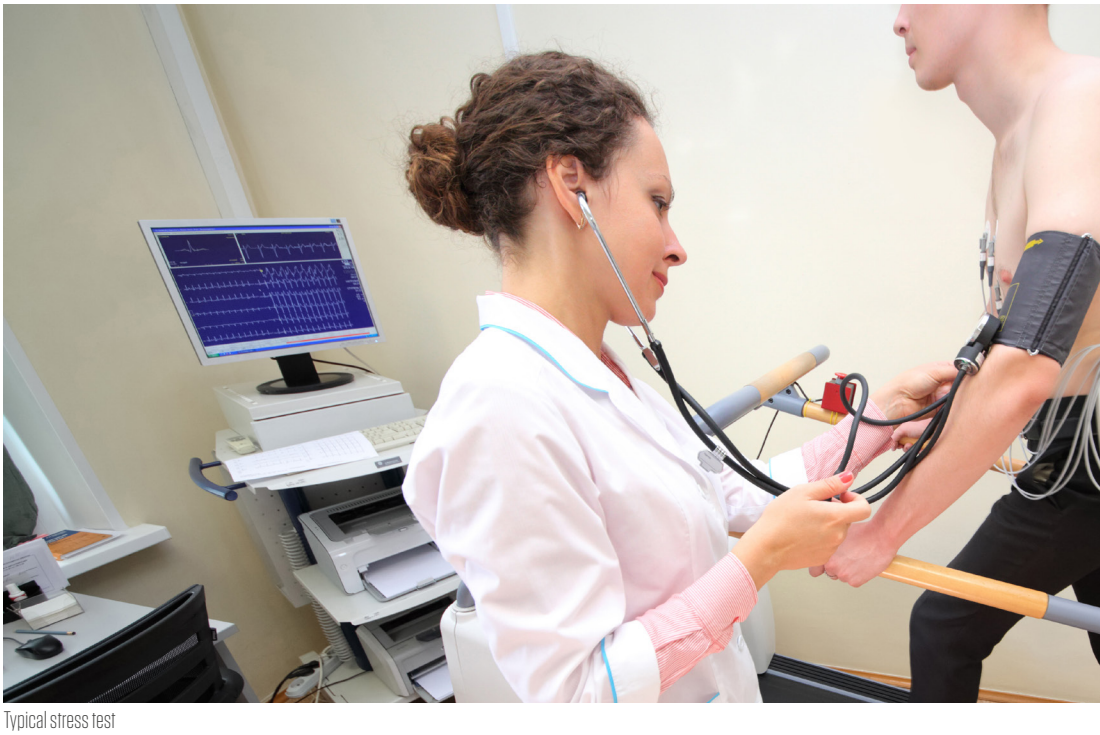
that with a great deal of engineering expertise applied to it, would accomplish this goal. As such, Patel and Tandar decided to contact James Thompson, director of the engineering team at TVC at the time, and asked if he knew anyone in the College of Engineering who could work with them on this project. Thompson knew exactly who to contact: Hanseup Kim, an associate professor of electrical and computer engineering at the U. When Thompson approached Kim and explained the project, Kim was intrigued and agreed to meet Patel and Tandar. In this meeting, which Thompson describes as "electric," Patel and Tandar told Kim what they needed the device to do, what the current clinical hurdles were, and what was needed to make the device acceptable to cardiologists. Kim responded by explaining current engineering limitations but also how he thought he could make this device a reality. "Within three hours," Kim explains, "we had come up with a plan for how to resolve the issues and meet the requirements."

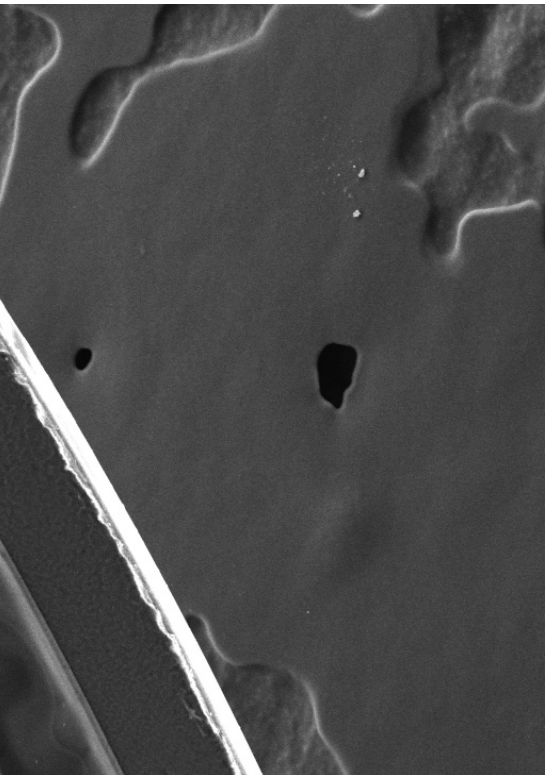
After a great deal of effort and time, the novel device that Kim came up with is a stent that non-invasively measures blood pressure along its length. It will be placed in arteries exactly like current stents so that cardiologists won't have to change the way in which they perform stenting procedures. Embedded on the stent's wires are pressure-sensing structures on the nanoscale (a scale operating at less than the width of a human hair). To read changes in pressure, an external device containing an electric current is activated and placed near the patient. As the current passes through this device, which the inventors call a "wand," a magnetic field is produced. This field induces

Another view of Kim, Tandar, and Patel's stent under a microscope





Typical stress test



James Thompson, interim director of TVC, helped connect Kim, Tandar, and Patel together

electrical resonance in the stent within the patient's affected artery. The wand measures changes in resonance frequency. Different resonant frequencies are associated with different levels of pressure buildup within the stent. Slower electrically-resonating stents are associated with higher pressure within the stent, indicating a likely buildup of plaque or a clot, while more rapidly vibrating stents are associated with less pressure, indicating more free-flowing arteries.

This method of reading pressure requires no batteries or electronics, making it durable and safe for patients. It should also allow for more routine visits that are non-invasive. These frequent visits will likely allow cardiologists to catch the beginning stages of restenosis or a clot developing, possibly saving lives, but almost certainly leading to better outcomes.

The next step for the device is for it to undergo experiments in live pigs. After this, the team will begin raising funds for clinical trials.

Tandar believes that the success of both the first meeting of the group as well as their subsequent interactions comes from the team's shared desire to solve this problem together regardless of recognition. "The more you work together, the better outcomes you will get," he explains. "We're far more interested in achieving better outcomes for our patients than getting credit." Adding to this, Patel explains, "These multidisciplinary team approaches can work. The key parts are realizing what you don't know and letting others with expertise in those areas do their part, and realizing that by yourself this can't be done."

OUTSIDE EXPERTS REVITALIZE LOW BACK PAIN DEVICE

TVC's Commercialization Engine helps to restart "Back Roll-ieve," a device designed to alleviate low back pain at home

TVC's Commercialization Engine Committee was formed in 2011 to help build a network of experts from which TVC could rely on to help advance U technology. Since that time, members of this committee have been responsible for many important commercialization advancements. One of these has been with a device designed by U physical therapists Tim Henry and Dave Carter to help people with chronic low back pain achieve relief at home.

Called "Back Roll-ieve," the device stretches the spine so that pressure is taken off of the spinal disks and the nerves in-between. To experience this relief, users unfold the compact unit to set it up, lie down on their back underneath its two front arms, align their hips with the device's front, attach a harness to their hips, rest their lower legs up on a tray that hangs from the top of the device, and then adjust the amount of stretching to the lower back by using harness height adjustment mechanisms on the side.

According to Carter, this stretching action, known as spinal decompression, or traction, may result in the relief of various types of low back pain such as stenosis, degenerative joint disease, and facetogenic pain.

Carter and Henry's device couldn't come at a more opportune time. Chronic low back pain amongst adults has increased significantly over the past 20 years. In 1992, 3.9 percent of Americans reported this condition. By 2006, this number had grown to 10.2 percent. It is also the second most common reason for disability in the U.S. and results in some 149 million lost workdays each year.[8]

According to Carter and Henry, it is common for physical therapists to check to see if spinal decompression will benefit a patient with low back pain. For those it does help, patients are often prescribed expensive treatment plans on costly decompression tables at physical therapy clinics of anywhere from 12 to 20 treatments, a range often defined and capped by insurance companies.

"The major impetus for us creating this device was our patients often asking us, 'How can I do these treatments at home? Spinal decompression really helps me,'" explains Carter.

Before developing Back Roll-ieve, Carter and Henry acquainted themselves with the various home back traction products on the market but believed that most were either potentially dangerous for certain people, too expensive,

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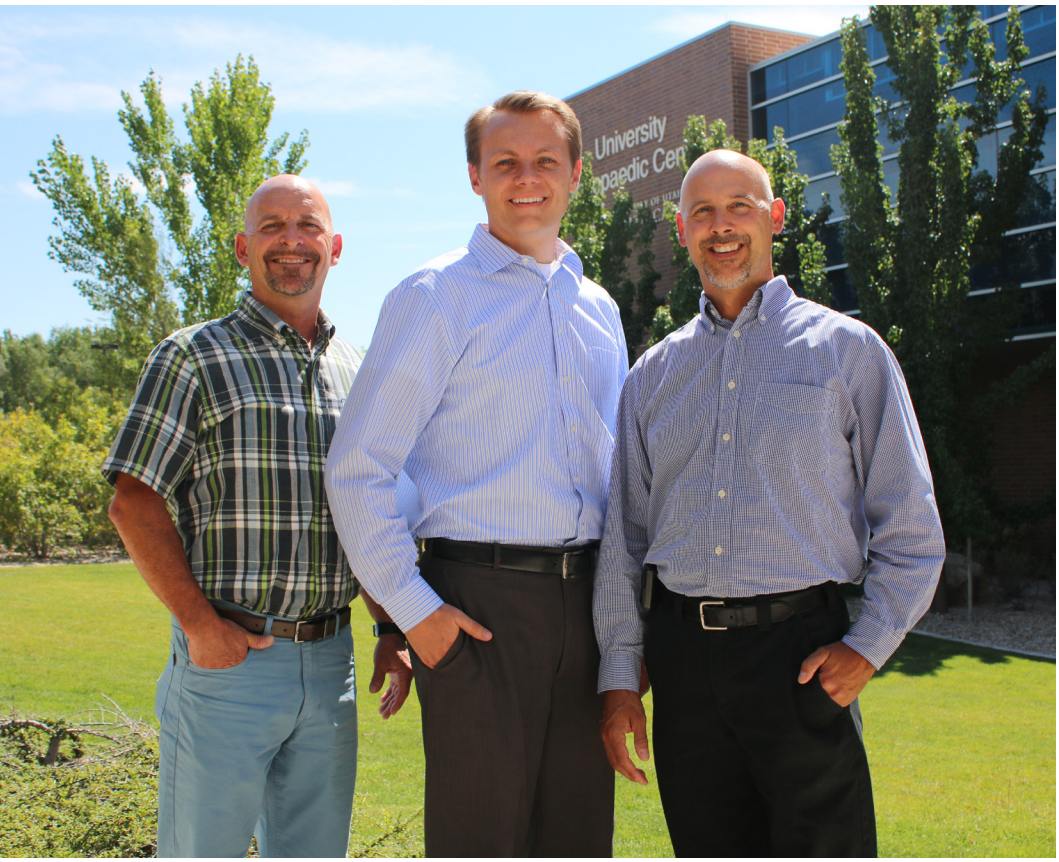
hard to use, or simply ineffective. As such, they decided to create their own device. The goal was to make it effective, easy to use, comfortable, and inexpensive.

ITERATIONS AND THEN SOME

Carter and Henry came up with the first design of their back traction device and disclosed it to TVC in 2012. In 2013, TVC awarded it with Commercialization Engine funds for prototype development. Carter and Henry used these funds to partner with a Chinese firm who built the device to Carter and Henry's specifications. "The result wasn't exactly what we were expecting," explains Carter. "The device was quite large and cumbersome. It would've worked great for Andre the Giant, but not so much for everyone else. It just didn't pan out."

Believing that Back Roll-ieve still had great potential, in 2015, Taylor Bench and Aaron Duffy of TVC decided that the device should be pitched to the Commercialization Engine Committee for another round of funding for further prototype development. This time, however, Bench and Duffy, in consultation with Carter and Henry, decided to seek outside engineering assistance. With a series of U inventions being rejuvenated by the growing number of external experts sitting on the Commercialization Engine Committee, Bench and Duffy decided to follow this path and contact a local precision engineering firm called Micron Solutions that had worked with TVC in the past. Daniel Pendleton, president of Micron Solutions, agreed to take on the project to design and manufacture a new prototype.



Inventors (left to right): Dave Carter, Daniel Pendleton, and Tim Henry

In the week leading up to the pitch before the Commercialization Engine Committee, Pendleton decided to make a cheap, wood-based prototype from Carter and Henry's original specifications. He showed it to Carter and Henry and told them, "This is to your dimensions. This is what you asked for." According to Pendleton, their reply was, "'This won't work. This isn't really what we had in mind.'" After this first version two more wood iterations of the device were made that same week. These three versions, as well as

the original prototype, were presented to the Commercialization Engine Committee as learnings for future development. "We told the Committee that this is what we've learned so far from the prototypes that were developed. We think we know where we need to go next; we just need the funds to do it," explains Pendleton.

After this presentation, Back Roll-ieve was awarded additional funds from the Commercialization Engine for further prototype development and Pendleton and his team at Micron Solutions got to work. Several different models with various heights and shapes were tried based on the original design but none of these worked. "The goal of these first few designs wasn't actually to come up with a final version," explains Pendleton. "Rather, the goal was to observe Carter and Henry using them, ask questions, and see what these designs could and couldn't do."

After this period of observation, Micron Solutions decided to take a step back and focus on the core of the device, rather than its design. "We asked ourselves, 'What are Carter and Henry trying to accomplish?'

The Back Roll-ieve device

'What is their mission?'" explains Pendleton. "A lot of engineers get anchored in a design. They try to make designs fit problems, but this rarely works. It's important to take the 30,000 foot view when engineering devices, and that's what we ultimately did here."

While this new approach largely meant abandoning the original design and its subsequent iterations, it also meant that Carter and Henry's original goals for the device would become more central than ever. With these objectives in mind, Micron Solutions created a completely new design of the device, one that Carter and Henry are quite pleased with. "We really have to pat Dan on the back for this latest design," says Carter. "We finally believe that the device is ready for testing."

ROLLING TO MARKET

In early 2016 the Back Roll-ieve team received additional funding from the Commercialization Engine. The goal of this funding is to make 10 prototypes and send them to various physical therapy clinics for testing and validation on patients. The feedback they receive from this testing will likely result in another version being made. After this, the goal is to make a more robust version for use in physical therapy clinics and, most importantly, a version for patients to use at home.

SEEDING SUCCESS WITH NEW MALE INFERTILITY TEST

Researchers from the Huntsman Cancer Institute, USC, and the U work together to create a new infertility test based on epigenetics

Couples struggling to conceive are often surprised to hear that half of infertility issues are on the male side. Sometimes the cause is straightforward, a blocked duct, chromosomal anomaly, or lifestyle factor. However, up to half the time, the cause is a frustrating unknown.[9]

Those one in four couples being treated for infertility have what appears to be healthy sperm based on traditional analysis, yet the sperm lacks the ability to fertilize and assist the egg through early development. For a long time, scientists and physicians had not been able to predict or explain why, leaving patients in the dark as they made expensive, emotional, and often invasive choices about their treatment without really knowing their odds of success. However, recent discoveries by U scientists point to epigenetics: modifications to the sperm's DNA sometimes caused by external factors and lifestyle choices such as the food we eat, physical activity, and aging that control which genes are turned on and off during and after fertilization.[10,11]

> **"DOCTORS CANNOT ACCURATELY DIAGNOSE MALE INFERTILITY. WE ARE NOW STARTING TO USE EPIGENETICS TO RECOGNIZE WHEN GENES AFFECTING FERTILITY HAVE BEEN ALTERED."**
>
> **—ALAN HORSAGER, CEO, EPISONA**

To Alan Horsager, president and CEO of U-spinout Episona, a molecular information company, the news of epigenetics' role in infertility called out for the development of a diagnostic test. He had been discussing how epigenetics affects neurodevelopment with Andrew Smith, associate professor of biological sciences at the University of Southern California. In this conversation, Smith mentioned some important infertility research by U scientists Bradley Cairns, professor of oncological sciences at the Huntsman Cancer Institute and Douglas Carrell, professor of surgery. "I thought, 'I'm going to call them up and ask whether there is an opportunity to develop a diagnostic test for male infertility based on epigenetic profiles,'" says Horsager. The combination of Horsager as scientist and entrepreneur, Smith's ability to navigate computational biology and analytics, Cairns' background in epigenetics and stem cells, and Carrell's clinical knowledge quickly lead to the development of technology based on their combined expertise.

"Doctors cannot accurately diagnose male infertility—basic semen analysis does not provide enough information. When

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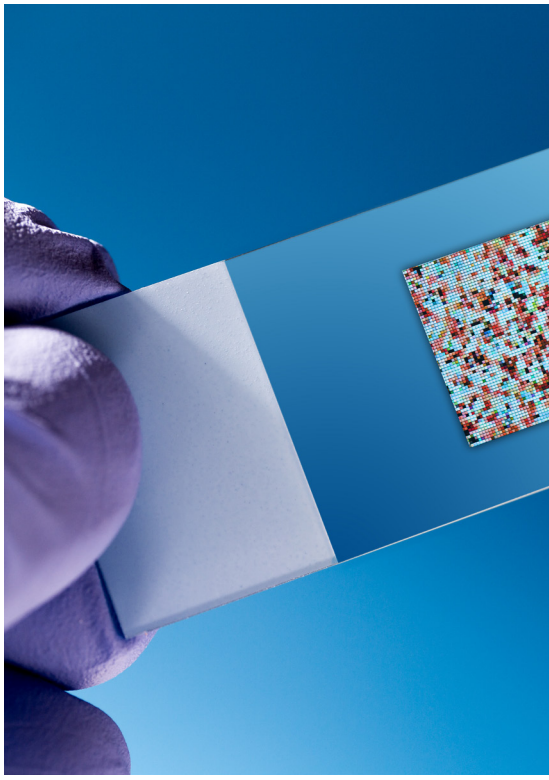
the sperm connects with the egg, the sperm basically melds into the egg. If that connection isn't happening properly, then you're not fertilizing properly and that's not going to show up on any analysis. Now we are starting to use epigenetics to recognize when genes affecting fertility have been altered," explains Horsager. The Carrell laboratory had been using microarrays and other techniques to pinpoint aberrant epigenetics in sperm of infertility patients. The collaborators looked to adapt the same techniques for use with individual patients, creating a test that would determine fertility at a molecular level.

The first product based on their collaboration is "Seed," a diagnostic test offered by Episona that both predicts fertility and identifies epigenetic abnormalities in fertility genes. Following up a successful pilot study last year, Episona is currently working with nine well-known fertility clinics to validate the technology. Patients will collect a sperm sample at home and send it to a lab that uses microarrays to analyze 480,000 regions of the epigenome, a map of compounds that attach to DNA and modify its expression. That information will be processed into an individualized report so the patient can review the results and treatment options with his physician.

The key to developing Seed, says Cairns, was the open nature of the collaboration between Smith, Cairns, Carrell, and Horsager. "You have a set of people who each come from different training backgrounds, so we all looked at this problem from a different perspective. At the end of the day we all wanted to figure out, 'How do you make a healthy baby?'"

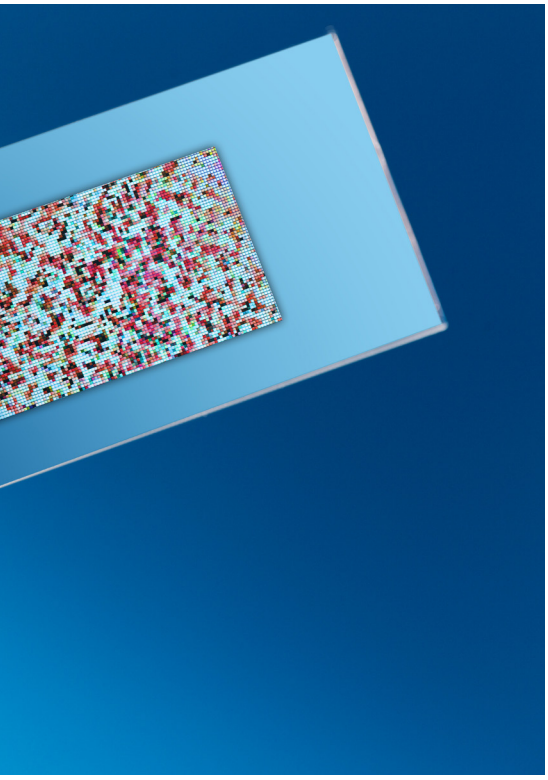
"I'm the intermediary between the science and the clinic so I'm

A microarray, a tool utilized by Episona

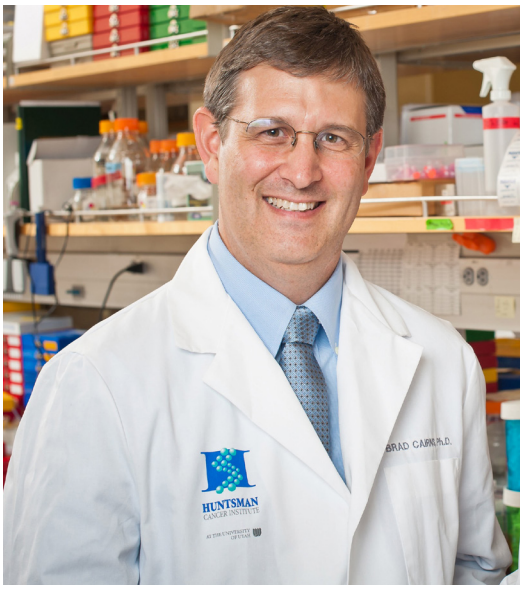


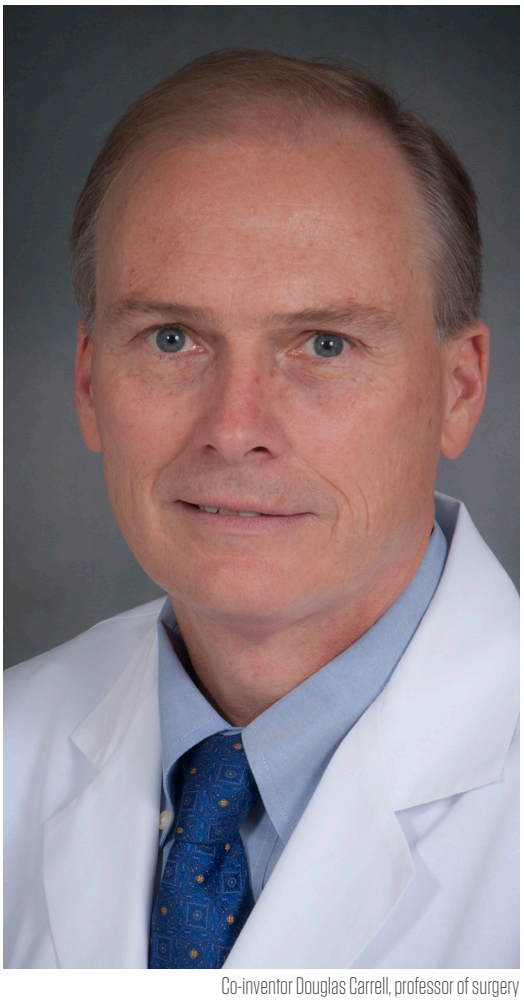
Collaborator Andrew Smith, associate professor of biological sciences at the University of Southern California

Fertility treatment counseling



Co-inventor Bradley Cairns, professor of oncological sciences





Co-inventor Douglas Carrell, professor of surgery

kind of building a bridge between what we see and what's really needed in the clinic," explains Carrell, whose work besides research includes directing the in-vitro fertilization (IVF) and Andrology Laboratories at the U. "We haven't really understood what's causing reduced fertility at the molecular and cellular levels. Genetics has answered some of our questions, but didn't go as far as we'd hoped. With epigenetics hopefully we'll go further and will understand what really is causing infertility and what we can potentially do to treat it."

Carrell predicts Seed will become a routine test at fertility clinics for couples that do not become pregnant after their first round of IVF. "It's heartbreaking for a physician to say, 'I have no idea whether the problem is the sperm or the eggs and cannot tell you the chances of failure for future attempts.' We have to give patients a better idea. Even if the results come back abnormal and the couple still wants to go through IVF, there are some clinical things that we can change to improve their odds."

TVC'S LEAN CANVAS PROGRAM EMPOWERS DEVELOPERS TO IMPROVE EAR IMAGING

An ear coil invention from UCAIR finds its path to market through the Lean Canvas method

Great ideas are plentiful. Of the seemingly infinite number of novel concepts, only a small number arrive at production, and even less prove to be marketable in the real world. For many new technologies, the defining factor of success or failure is often whether or not their creators verified that they would meet an actual need in the market. This common polarity is typically amplified in academia where many well-meaning researchers work out their novel ideas without consideration of the particular needs of those who will use them. The Lean Canvas program at TVC began in an effort to connect real market needs with real answers. Instead of flooding the market with ill-matched solutions, the aim is to arm researchers with an end-user's mindset.

As part of the Lean Canvas program, teams—which apply to get into the program with their business and technology development manager at TVC—take an online course entitled "How to Build a Startup: The Lean Launchpad," in which they learn from bestselling author and serial entrepreneur Steve Blank about his customer development process. This course is augmented with in-person classes at TVC led by local startup expert Phil Grimm. Through this course, Blank and Grimm share their experiences of building successful startups and bringing concepts to fruition by paying close attention to customers and their needs. Armed with a drawdown budget of $4,500, teams are then tasked to canvas for feedback from as many potential customers and experts in the industry as required to validate their idea (some teams with specialized products need only a dozen or so interviews while others with a more broad appeal need as many as 150). With this funding, teams can develop prototypes, attend conferences, and travel to present their concept to potential customers and industry professionals in order to glean their insights and potential modifications.

As a result of the Lean Canvas program, a group from the Utah Center for Advanced Imaging Research (UCAIR) called WICS (Wasatch Integrated Coil Solutions) was empowered to pivot their original technology to respond to a new and verified market need. This team, led by Rock Hadley, research assistant professor of radiology and imaging sciences at the U and co-inventor of WICS, had originally developed an MRI coil that would generate high-performance images of the inner ear, primarily to capture photographs of the cochlea, an area he knew was difficult to image.

When the team entered the Lean Canvas program in early 2016, they began doing dozens of interviews with the

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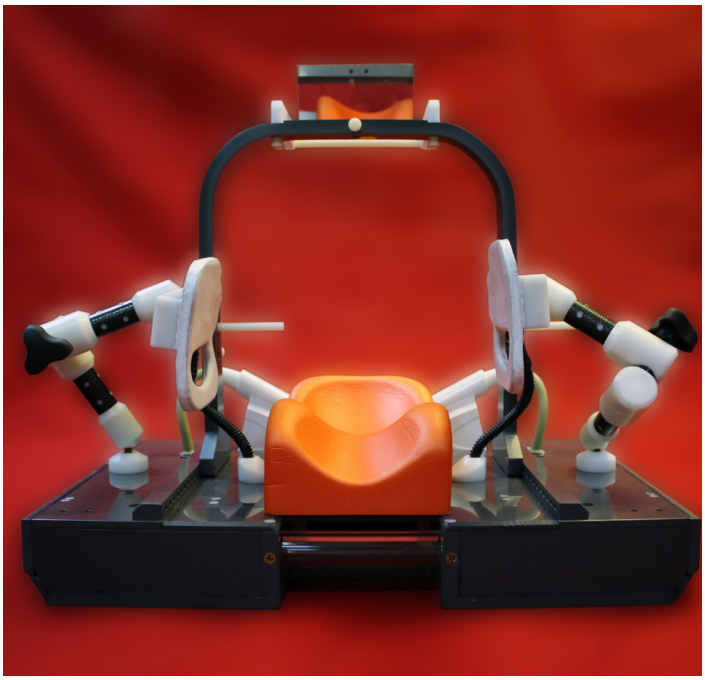
end-users of their coil: radiologic technologists. The team quickly learned that these technologists would not adopt WICS' coil for use in their practice. "The technicians repeatedly explained to us that they didn't want to switch coils on the patient table if they didn't have to," explains Hadley. "They told us, 'we're never going to use this ear coil; it will simply take too much scanner time and we have too many people to scan.'"

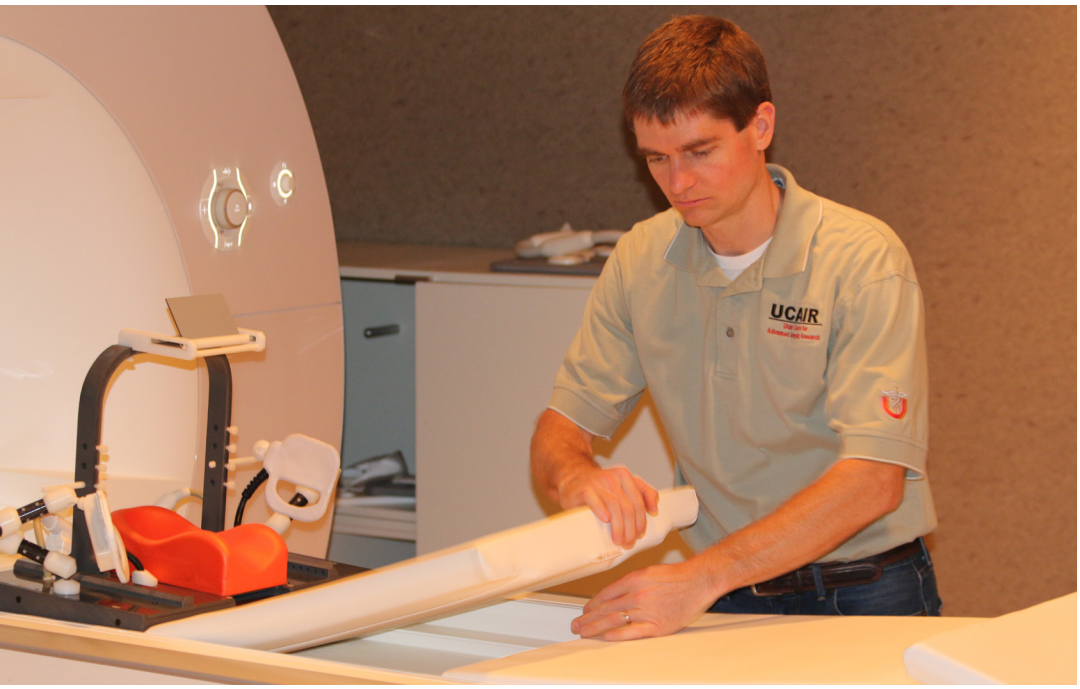
Further conversations with the technologists and physicians—which are required of technologies that require a change in direction due to the results of the first round of interviews—yielded two important insights. First, if simple modifications could be made to the coil that would make it quick and easy to use, the technologists would indeed use it. Second, if the team could modify the coil such that it could capture clear, high-resolution images of the inner chambers of the cochlea, physicians would order its use when trying to diagnosis Meniere's disease, a condition that afflicts patients with symptoms such as dizziness, vertigo, and persistent ringing in the ear.

The WICS' ear coil



(left to right) Robb Merrill , Rock Hadley, and Emilee Minalga, each a member of the group that developed the ear coil

Robb Merrill of UCAIR installing the WICS ear coil on an MRI machine



from potential customers and experts has been fundamental to the early success of the Lean Canvas program. These interactions are providing critical and actionable feedback to researchers and developing important synergistic relationships with outside groups and individuals that are together becoming essential to commercializing U technologies.

Armed with these valuable insights and data gathered from the Lean Canvas Program, the WICS team is now pursuing further grants and opportunities with the National Institutes of Health (NIH).

> **"[THE RADIOLOGIC TECHNOLOGISTS] TOLD US, 'WE'RE NEVER GOING TO USE THIS EAR COIL; IT WILL SIMPLY TAKE TOO MUCH SCANNER TIME AND WE HAVE TOO MANY PEOPLE TO SCAN.'**
>
> **—ROCK HADLEY, RESEARCH ASSISTANT PROFESSOR OF RADIOLOGY AND IMAGING SCIENCES AND CO-INVENTOR OF WICS' TECHNOLOGY"**

With further funding, the WICS team hopes to further improve resolution and imaging as well as work at adapting their ear coil into a more clinical-friendly headset.

Technology pivots in response to verified market needs, such as what the WICS team experienced, are becoming a common occurrence in the Lean Canvas program at TVC. These crucial shifts are reviving U technologies and moving previously neutral ones forward. None of this could happen, however, without the interactions the U's technologies are increasingly having with the community. The requirement that each team obtain a substantial number of interviews

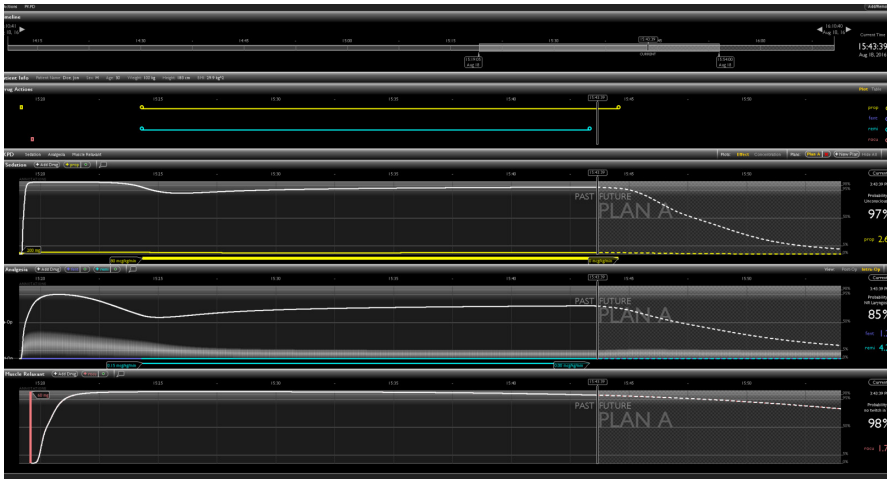
Co-inventor Rock Hadley, research assistant professor of radiology and imaging sciences

MEDVIS SIMULATES BETTER DEVICE DEVELOPMENT

While medical device inventors routinely generate innovative, even groundbreaking ideas, they often need assistance transforming these ideas into successful products that improve patient care. That assistance is increasingly taking the form of ensuring that the end users of these devices can easily learn and incorporate new technology. It means making sure that busy clinicians do not have to fiddle with technology, that patients do not have to worry about complex instructions, and that both benefit from improved efficiency and lowered costs.

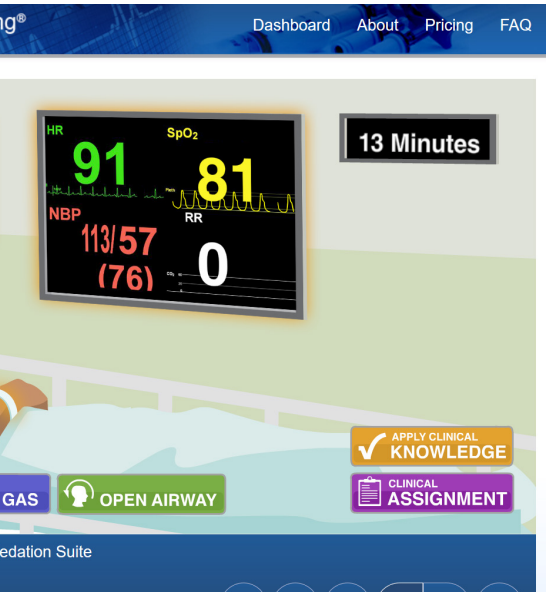
Applied Medical Visualizations (Medvis) is a U-spinout born of the need to improve medical technology so that it can be more useful. While the U.S. Food and Drug Administration once

Screenshot from one of Medvis' simulations



Co-inventor Noah Syroid of Medvis during a simulation

Co-inventor Jim Agutter, assistant professor of architecture



Screenshot from Medvis' Safe Sedation Training Software

recommended usability tests, the agency recently made it a mandatory part of applying for medical device approval.[12]

"We have to look at technology in terms of how useful is it to clinicians. If it is not useful, how do we change it?" says Jim Agutter, assistant professor of architecture and CEO of Medvis, which develops software, evaluates usability, and uses a combination of the two to develop innovative healthcare training.

Early on Agutter and business partner Noah Syroid began working with Dwayne Westenskow, then director of the Anesthesiology Bioengineering Laboratory at the U. Westenskow was researching the visualization of anesthesia patient monitoring technology, or how clinicians track the waveforms and numbers generated by the patient's body while under anesthesia during surgical procedures.

Westenskow had received a NIH grant to develop new technology in the operating room. "The team thought, 'There's got to be a better way to do this that presents the information in a way that supports the clinician's mental model so they can make better decisions,'" explains Agutter. To achieve this, Westenskow consulted with experts from a diverse range of fields, including psychologists and architects such as Julio Bermudez, then an associate professor of architecture at the U, who also had an interest in the visualization of complex information. The team also worked with Stefano Foresti and utilized the resources at the Center for High Performance Computing. In this way, Medvis is a highly interdisciplinary effort that reflects the collaborative problem-solving emphasis at the company.

"We are really fortunate to be surrounded by amazing collaborators with a variety of skills. Depending on the project we ask, 'Who do we need at any given time to help solve these complex problems?' We can bring all these different perspectives together when needed. This approach is much better, much richer than if we all came from the same background," explains Agutter.

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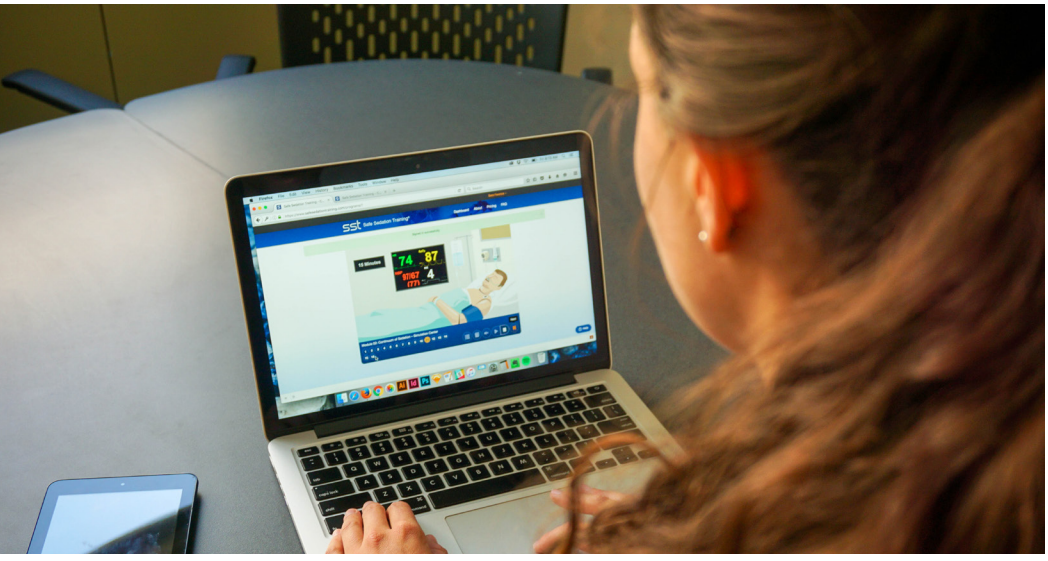
"A fundamental basis of the company is solving problems from an interdisciplinary perspective. Instead of putting up walls, we've worked to tear them down," says Noah Syroid, Chief Technical Officer. "I'm an engineer and can build this cool technology, but the things in my mindset wouldn't necessarily work for clinicians. It doesn't always match what's happening with the clinician and the patient. There are all these other steps involved in design and the psychology of a mental model."

Agutter and his colleagues found ways to improve visualization, which they patented and then licensed to large medical manufacturers in collaboration with the U. While working on the anesthesia project they realized that developing usability tests and evaluating technology in a simulated medical environment could be a valuable service.

"Companies often have a lot of great engineers but are not close to the clinic," says Agutter. "Because we have Drs. Talmage Egan and Ken Johnson as business partners, we have an insight and understanding of the clinical problems and workflow that is very deep. This allows us to develop solutions that solve real clinical problems."

Along with improving the usability of medical technology, based upon a need identified by partner Dr. Talmage Egan, they created what would become one of Medvis' core products, moderate sedation training. Many medical and dental procedures that involve light anesthesia do not require a fully trained anesthesiologist but they do require a clinician who knows how to use the drugs and monitoring technology. Until Medvis introduced its Safe Sedation Training (SST), no widely accessible, standardized training was available to sedation practitioners.

Medvis developed a standardized curriculum to train clinicians who provide sedation. "You want to avoid on-the-job training by having clinicians try it out in a simulated environment before they work with a real patient," explains Agutter. After completing a didactic course and watching demos, the trainees walk through patient simulations. The course has become a mandatory part of training for many U healthcare providers and Medvis has had large contracts to train clinicians from outside the U as well. The SST training is endorsed by several major anesthesiology societies.



A student using Medvis' Safe Sedation Training program

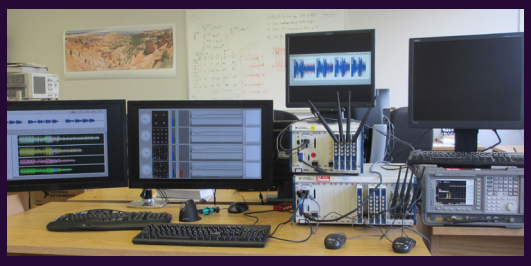
2016 SPINOUTS

Over 175 companies have been launched from U technologies in the last ten years, and more than 275 since 1970. These diverse companies range from the fine arts to pharmaceutical chemistry. The following are some of the newest created at the U:

1 *Blacksand Technology*

Blacksand Technology was founded to commercialize new titanium production methods developed at the University. Blacksand's process is aimed at making low-cost, high-quality titanium powder for use in emerging methods of manufacturing parts for aerospace and medical implants.

2 *Farhang Wireless*

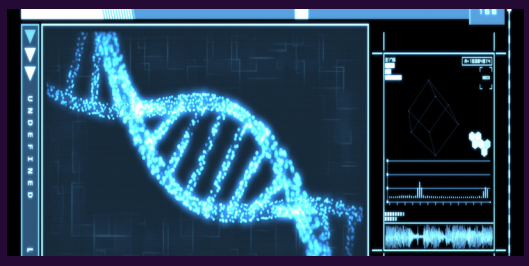


Farhang Wireless develops advanced solutions for the cellular, WiFi, and custom wireless communications industry. Through partnering, consulting, and licensing our goal is to use our core strength in signal processing to develop and proliferate market leading technology.

3 *Fluidx Medical Technology*

Fluidx's GPX product is a new multi-use non-cytotoxic embolic designed to improve effectiveness, safety, and delivery. GPX combines the benefits of coils, particles, and liquid embolics and has demonstrated to be effective in occluding vasculature from capillary to 6mm in bench and in-vivo studies.

4 *Frameshift Labs*



Frameshift Labs is a company dedicated to building cloud-based, visually driven, genomic analysis tools to facilitate discovery of diseases and diagnostic tests based on genetic variation. Their easy to use, web-based tools eliminate the need for expensive hardware and staff to maintain it.

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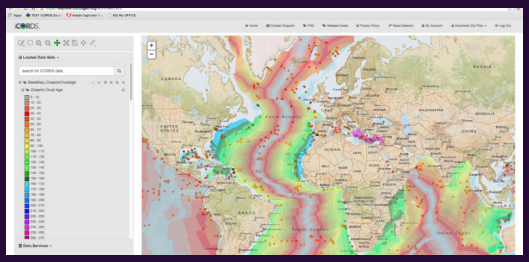
5 *iCORDS*



iCORDS is a spinout from the Energy & Geoscience Institute (EGI) at the U. The company offers an easy-to-use cloud-based knowledge platform that facilitates interactive access to both proprietary EGI oil and gas exploration data and curated publicly available data of the same.

6 *ItRunsInMyFamily.com*

Family health history (FHx) is one of the most important risk factors for cancer and the foundation of genomic medicine, but is under-utilized by patients and clinicians. ItRunsInMyFamily.com uses artificial intelligence and social networking to help family members link up and share health information with each other to improve FHx collection.

7 *Polarized Antenna Innovations*

Polarized Antenna Technology offers a duel polar antenna that provides clearer sound on the calls, fewer dropped calls, and an increased ability to pick up signals in previously dead areas. Studies show a 50% recovery of rotation induced distortions and drops.

ENDNOTES

1. David Russell Schilling, "Knowledge Doubling Every 12 Months, Soon to be Every 12 Hours," Industry Tap, April 19, 2013, accessed July 28, 2016, http://www.industrytap.com/knowledge-doubling-every-12-months-soon-to-be-every-12-hours/3950.
2. William B. Dabars, "Disciplinarity and Interdisciplinarity: Rhetoric and Context in the American Research University" PhD diss., University of California, Los Angeles, 2008, ProQuest/UMI (3347020).
3. "Tuberculosis," World Health Organization, March 2016, accessed August 5, 2016, http://www.who.int/mediacentre/factsheets/fs104/en/.
4. Gina Kolata, "Putting Stents to the Test," *New York Times*, June 22, 2015, accessed August 5, 2016, http://www.nytimes.com/2015/06/23/health/heart-attack-stent-angiogram-chest-pain-angina.html?_r=0.
5. "Heart Disease," Centers for Disease Control and Prevention, accessed August 5, 2016, http://www.cdc.gov/nchs/fastats/heart-disease.htm.
6. Scott Maier, "Patients With Heart Stents Have Similar Increased Risk of Death from Bleeding and Heart Attacks," University of California at San Francisco, April 7, 2015, accessed August 5, 2016, https://www.ucsf.edu/news/2015/04/124976/patients-heart-stents-have-similar-increased-risk-death-bleeding-and-heart.
7. Ehrin J. Armstrong and John R. Laird, "Treatment of Femoropopliteal In-Stent Restenosis for Patients With Diabetes: Do We Have an Answer to the DEBATE?," *Journal of Endovascular Therapy* 21, no. 1 (February 2014): 9-11.
8. Janet K. Freburger, George M. Holmes, Robert P. Agans, ,Anne M. Jackman, Jane D. Darter, Andrea S. Wallace, Liana D. Castel, William D. Kalsbeek and Timothy S. Carey, "The Rising Prevalence of Chronic Low Back Pain," *Archives of Internal Medicine* 469, no. 3 (February 2009): 251-258.
9. "How Common Is Male Infertility, and What Are Its Causes?" Eunice Kennedy Shriver National Institute of Child Health and Human Development, last modified Nov. 11, 2012, accessed July 10, 2016, https://www.nichd.nih.gov/health/topics/menshealth/conditioninfo/Pages/infertility.aspx.
10. Kenneth I. Aston, Philip J. Uren, Timothy G. Jenkins, Alan Horsager, Bradley R. Cairns, Andrew D. Smith, Douglas T. Carrell, "Aberrant Sperm DNA Methylation Predicts Male Fertility Status and Embryo Quality," *Fertility and Sterility* 104, no. 6 (December 2015): 1388-1397.e5.
11. "The Young Sperm, Poised for Greatness," Huntsman Cancer Institute at the University of Utah, May 18, 2014, accessed July 10, 2016, http://healthcare.utah.edu/publicaffairs/news/2014/05/05-18-14-Young-Sperm-Totipotency.php.
12. "Premarket Information - Device Design and Documentation Processes," U.S. Food and Drug Administration, accessed July 30, 2016, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HumanFactors/ucm119190.htm.

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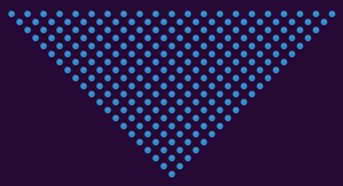
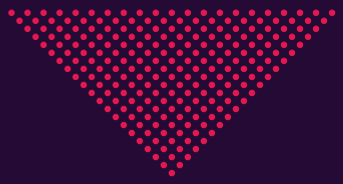
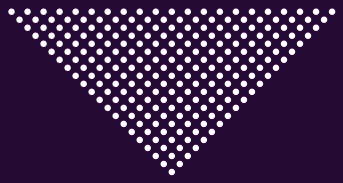
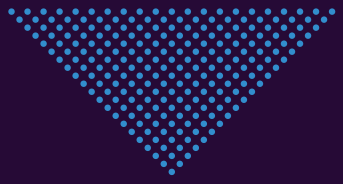
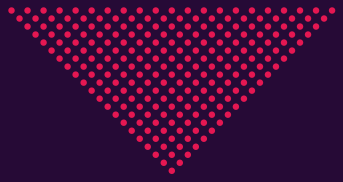
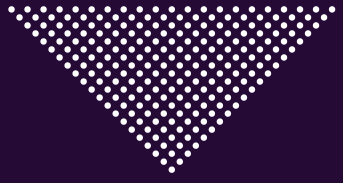

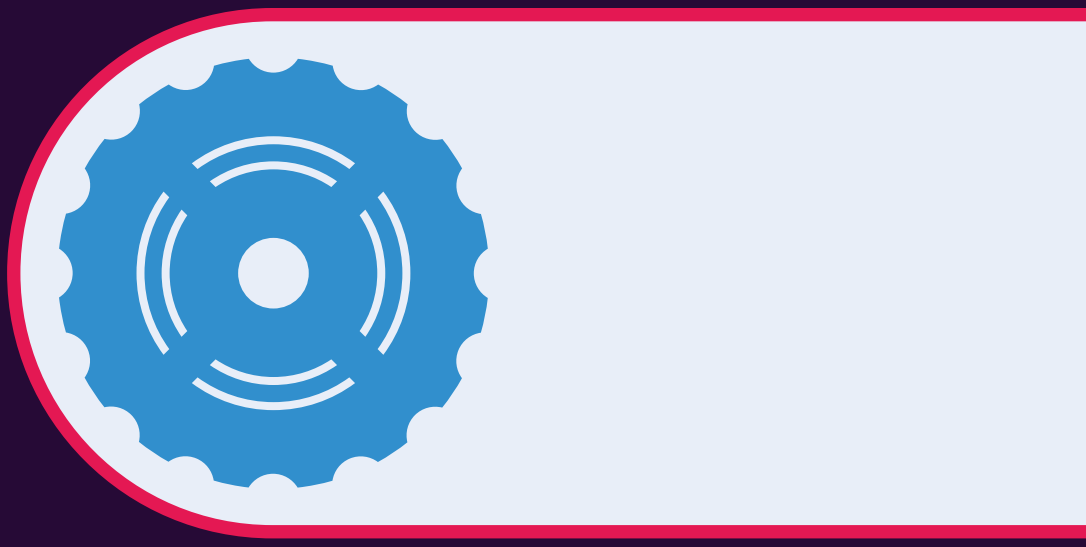

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