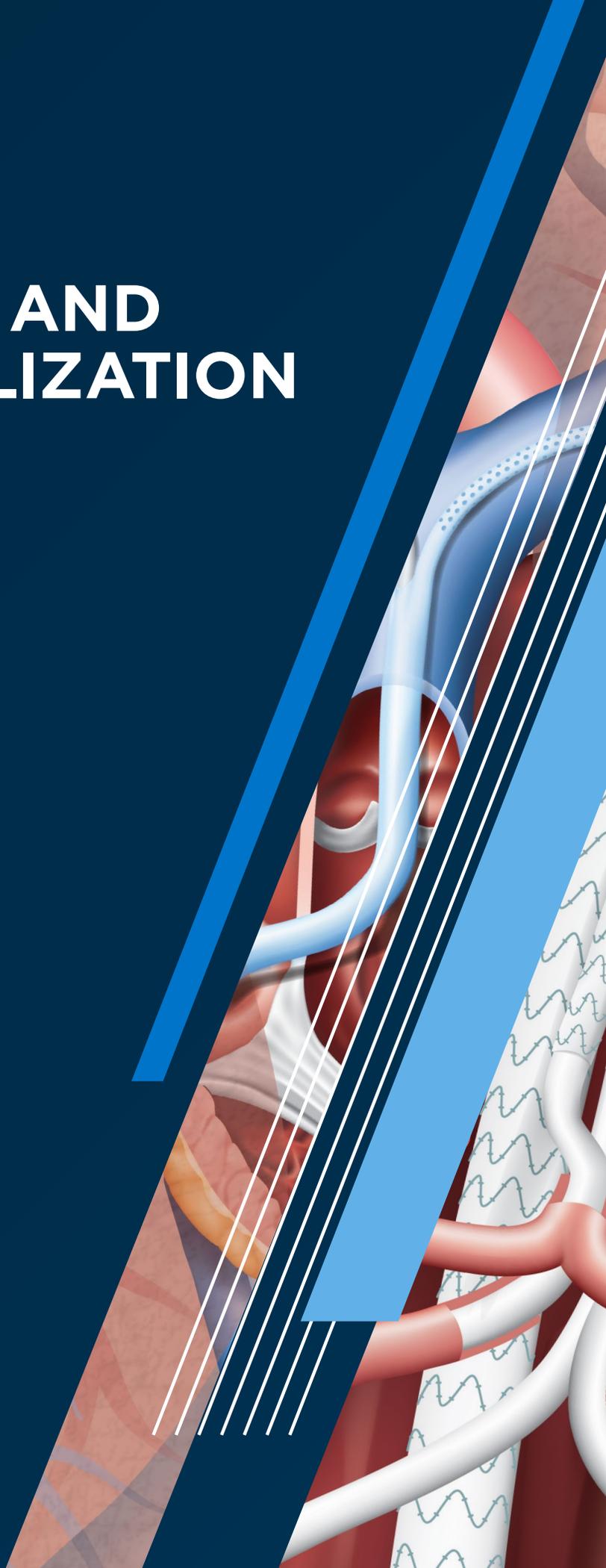


INNOVATION AND COMMERCIALIZATION

2021 ANNUAL REVIEW

SANFORD[®]
HEALTH



INNOVATION AND
COMMERCIALIZATION

ANNUAL REVIEW

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That describes the purpose of Sanford Health's innovation and commercialization team well.

It began in 2008 and has morphed into an embedded, collaborative, creative and multidisciplinary team. We help nurses, physicians, advanced providers, researchers and other employees develop solutions to problems, identify efficiencies, improve safety and discover new ways of caring for our patients, residents and customers in the 26 states and 10 countries we serve.

When someone in the clinical or nonclinical space comes up with a better way to do something, we work alongside that person to develop the idea internally or partner with outside experts.

Rather than a top-down approach, Sanford Health believes the best ideas come from the front lines and align with the organization's strategic priorities, which is why the innovation and commercialization team is a vital part of the country's premier rural health system.

In everything we do, we strive to support the **Sanford Standard**, our promise of a higher level of service and exceptional patient care.

The following annual review demonstrates how we accomplished that in 2021.

MOST GREAT
ADVANCEMENTS IN ANY
INDUSTRY START WITH
AN IDEA, ARE REFINED
OVER TIME AND FLOURISH
INTO SOMETHING THAT
BENEFITS SOCIETY.



2021



In corporate language, “innovation” can be a buzzword. It can take on different meanings to help a company tell its story, be overemphasized at the cost of performance or underemphasized to the detriment of the future. Still, innovation is necessary for a company to evolve, survive and compete. I don’t have to recite the many stories of companies that either got innovation right and thrived or got it wrong and are no longer around.

What separates those companies that got it right from those that end up in business books as examples of what not to do? I believe the difference is in how openly a company embraces innovation, makes it part of the culture and integrates it within the fabric of the organization.

Sanford Health has a history of and commitment to innovation that we continued to build upon in 2021. We restructured our team to better align and integrate with the rest of the organization, reflecting our priority of supporting the vision and strategy of the enterprise. Our new structure helps us effectively and efficiently embed our resources in the right places, keeping us focused on innovations that have the greatest impact.

Our commitment to innovation goes beyond structure and to our talented team of experts who helped lead invention disclosures, new patents and the creation of three new companies in the past year. In this annual review, you will learn about two Sanford Health nurses who worked with the innovation and commercialization team to patent an invention inspired by challenges following their father’s surgery. You’ll read the story of three Bismarck physicians collaborating with a startup company to develop new artificial intelligence algorithms that help detect cancer sooner, when it is more treatable.

These are just a few of the dozens of examples that prove innovation is not just a buzzword here, but instead that Sanford Health is taking a purposeful approach to build a culture and focus on innovation across the organization. As we look forward, we will continue to ensure that our innovation and commercialization strategy is positioned to help make Sanford Health the premier rural health system in the country and beyond. Our patients, people and communities deserve this commitment.

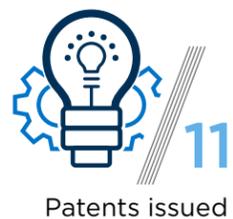
Kent Lehr
Chief Business Development Officer

INTELLECTUAL PROPERTY DASHBOARD

Ultimately, our success comes from the wide range of ideas brought to us by a diverse group of engaged employees. Here are the metrics we use to track our performance since the department's formation in 2008 and in the past year.



SINCE
DEPT.
INCEPTION

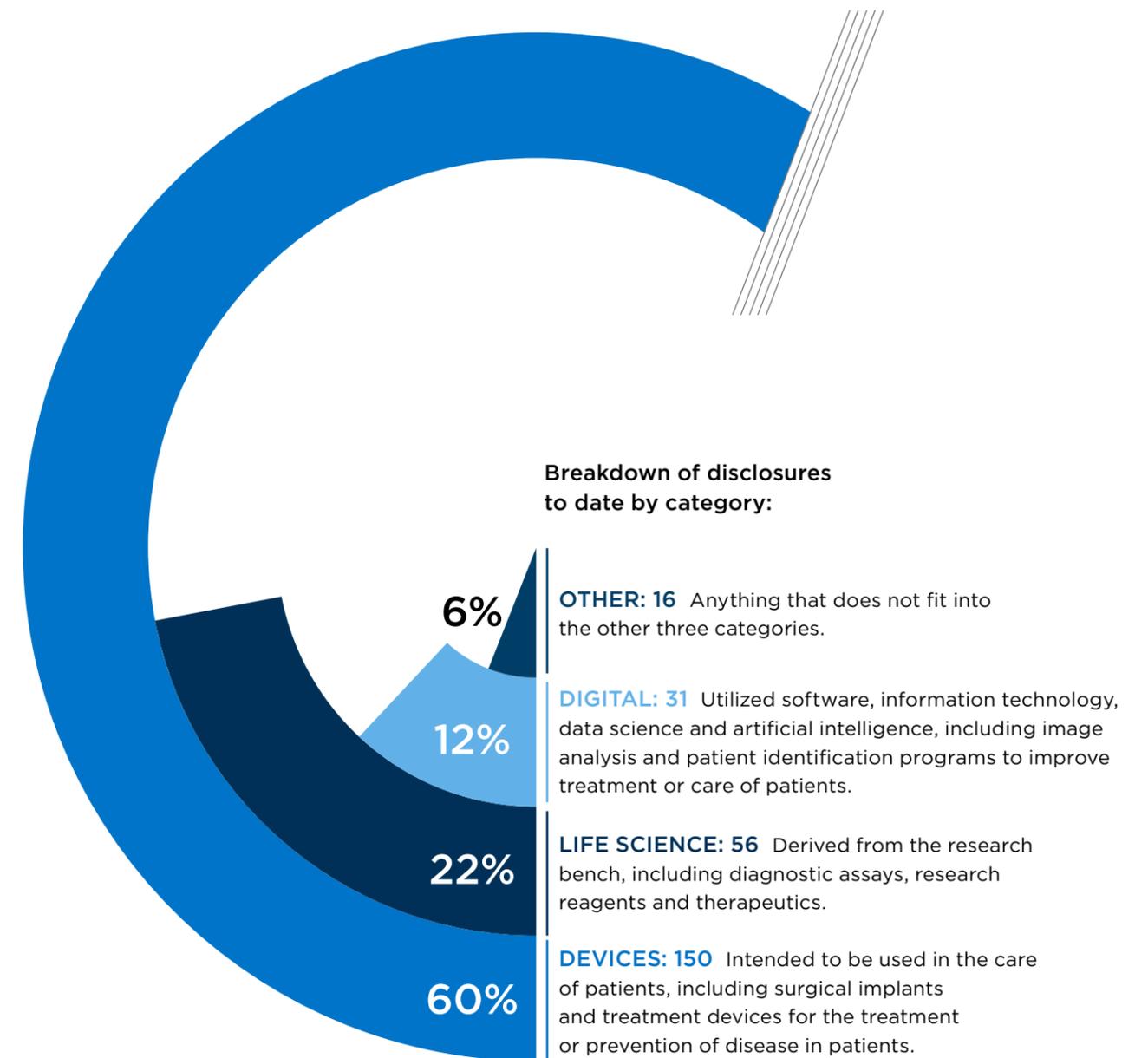


2021

INVENTION DISCLOSURES BY TYPE

In 2021, ideas came from Fargo (31%), Sioux Falls (20%), Enterprise Data and Analytics (14%), Research (14%), Bismarck (6%), Clinic Administration (3%), Supply Chain (3%), Technology Solutions (3%), Human Resources (3%) and Clinics (3%).

Since the department's inception, 253 invention ideas have been disclosed to the innovation and commercialization team.



*Neither Sanford Health nor the inventors received royalties on any products sold to Sanford Health

A key element of innovation is the refinement and validation of the idea: prototype, tweak, test, and go back to the drawing board until it's ready to be marketed or deployed.

One of the best pathways to do that is to build the idea into a startup company owned by the inventor(s). This process helps develop new technologies beyond the napkin sketch phase, sometimes to the point of generating clinical data, which helps de-risk the innovation and make it more attractive to established industry partners.

Several Sanford Health physicians, nurses and researchers have created such businesses through our new express startup program that launched in late 2020, with several other new spinoffs in the works.

STARTUPS



STERNUM PROTECT

The latest spinoff, D3D, comes from sisters Amanda Rollag, RN, (left) and Angel Rollag, LPN, both Sanford Health ambulatory nurses in Sioux Falls, who came up with a pad that protects patients who have had surgery requiring a sternotomy, an incision made through the breastbone. They were inspired to create the device, called Sternal Protect, when their late father struggled after open-heart surgery. The current protocol is to have patients hold a towel to their chest. The pad offers a hands-free alternative. They hope to make it available to patients starting in 2022.



THOMAS HALDIS, DO
ALEXANDER DROFA, MD

SLIDE GUIDE CATHETER

Fargo surgeons Thomas Haldis, DO, an interventional cardiologist and medical director of the cardiac cath lab, and neurosurgeon Alexander Drofa, MD, invented a device called the Slide Guide Catheter that could simplify stroke treatments. Their company, Flotronic Solutions, has a working prototype that will be refined as it seeks clearance from the U.S. Food and Drug Administration.

RIB FIXATION DEVICE

Fargo trauma surgeon Steven Briggs, MD, started the third company under Sanford Health's startup program, Blue Sky Holdings. He developed rib fixation devices that could allow a surgeon to repair broken ribs by making a small incision and drilling through the soft bone marrow to insert a wire or bit to stabilize the broken bone from within. The approach is less invasive than the current protocol of affixing metal plates to the outside of the broken rib. The company is in the process of refining the prototype so it can be tested.

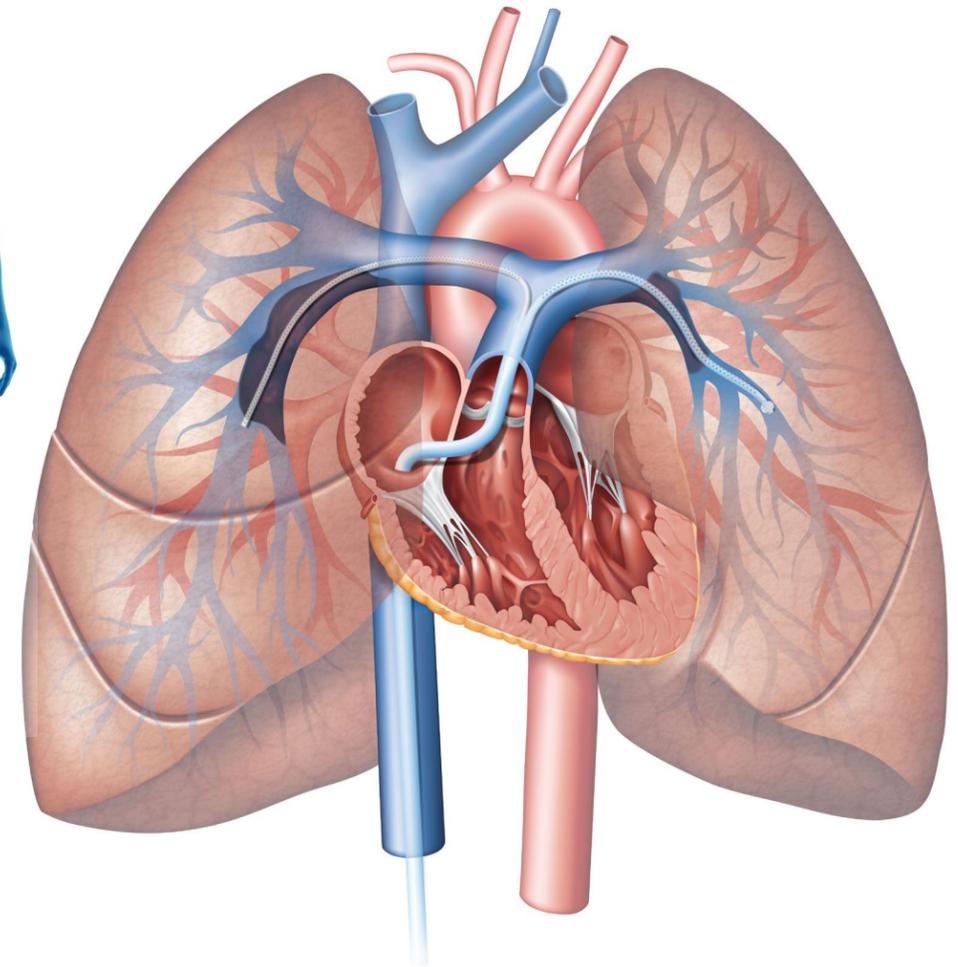
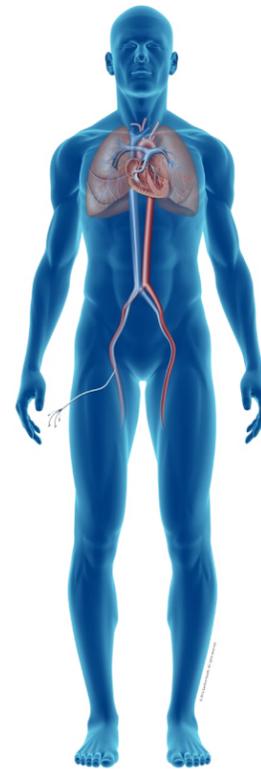


STEVEN BRIGGS, MD

MAPPeR

Parsli was founded by Adam Emerson and Adam McDermaid, PhD, to commercialize the Meaningful, Actionable Pharmacogenomic Patient Results (MAPPeR) technology invented by clinical data scientists at Sanford Imagenetics. McDermaid and Murat Sincan, MD, director of computational medical informatics at Sanford Imagenetics and assistant professor at the USD Sanford School of Medicine, invented the MAPPeR tool to assist genomic medicine clinicians with patient selection for pharmacogenomic testing services. MAPPeR identifies the patients likely to have a medication or dosage change based on their clinical profile, alerting their physician that pharmacogenomic testing may improve their care.

In addition to Sanford's internally developed inventions, several outside companies have partnered with or licensed medical devices that were invented at Sanford Health.



PATRICK KELLY, MD

DRUG-COATED BALLOON

A drug-coated balloon developed at Sanford Health and the University of South Dakota could be limb-saving for many of the 83,000 Americans who undergo a procedure each year to increase blood flow to the lower legs. Startup company Tailored Medical Devices in Sioux Falls has licensed the balloon and is raising money to further develop and test the device that may deliver drugs to specific arteries more precisely. It's based on intellectual property jointly created by Sanford Health vascular surgeon and inventor Patrick Kelly, MD, and Gopinath Mani, PhD, formerly of USD, as well as contributors Tyler Remund of Sanford Health and Sujana Lamichhane and Jordan Anderson, also formerly of USD.

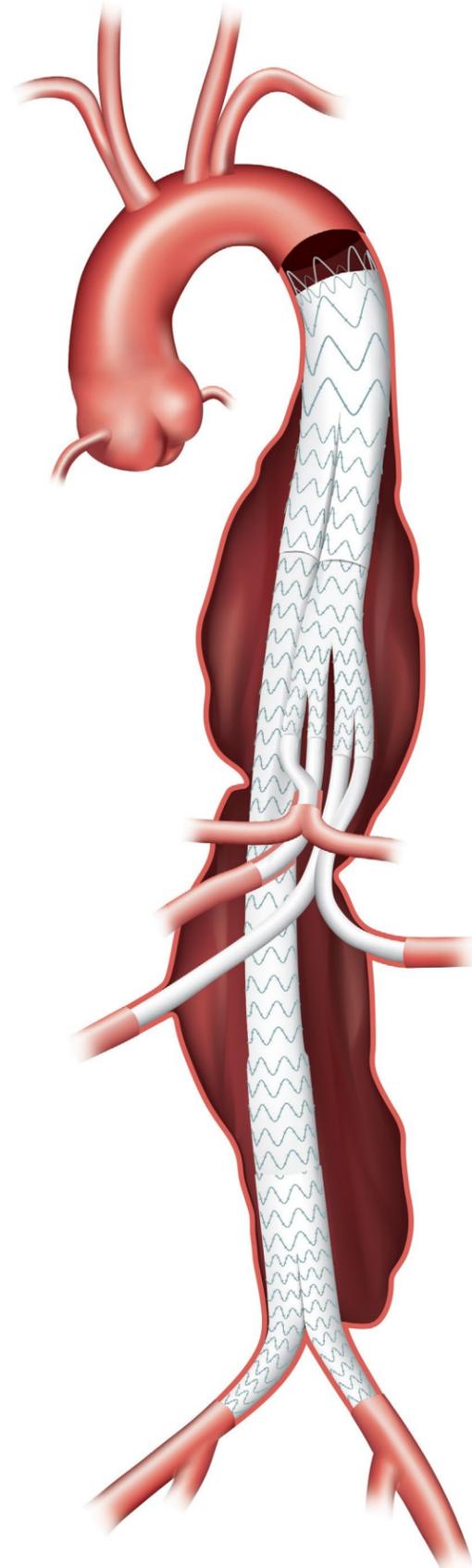
PE CATHETER

Another device invented by Dr. Kelly, the pulmonary embolism (PE) catheter, was licensed to startup company Lique Medical Inc., whose leaders are raising capital and plan to commercialize the device and obtain clearance from the FDA. The less invasive catheter simplifies the treatment of blood clots in the lungs that kill as many as 100,000 Americans each year. Specifically, the device requires one incision in the groin rather than two.

PARTNERS

AORTIC STENT GRAFT

In 2021, the Food and Drug Administration designated an aortic stent graft invented by Dr. Kelly as a breakthrough device because it fills an unmet need — a rare honor for a health system. It is designed to treat a thoracoabdominal aortic aneurysm, or TAAA, a complex condition that causes a dangerous bulging of the aorta extending from the chest down into the abdomen. The device has the potential to open the door to more people seeking minimally invasive aortic treatment.



INANOVATE

Inanovate licensed a breast cancer biomarker panel invented at Sanford Research that aims to create a mammography companion diagnostic and a recurrence detection test. The company relocated to Sioux Falls in 2018 and since that time has made immense progress in clinical sample collection, quality systems and regulatory submissions. Inanovate's proprietary technology involves a multiplex analyzer, which is now being produced under an established quality system at a contracted device manufacturer. This development grants Inanovate an investigational device exception, which means the biomarker panel can be deployed with approval in a clinical study to help determine the technology's safety and effectiveness.

SAFETY FOLEY URINARY CATHETER

A modified urinary catheter to reduce pullout injuries, invented by Bismarck radiologist Bruce Gardner, MD, was licensed to InnoCare Urologics, a company whose founder co-invented technologies for the angioplasty balloon and coronary stent. The company has agreed to develop, manufacture and sell the catheter device that's designed to trigger the retention balloon inside the user's bladder to deflate nearly instantaneously when tension

is applied to the external tubing. Gardner said he's honored to have his invention picked up by a company founded by Leonard Pinchuk, winner of the prestigious Russ Prize in 2019 for his invention of the angioplasty balloon.



BRUCE GARDNER, MD

REGENERATIVE MEDICINE: INGENERON

Five years after Sanford Health's first-of-its-kind clinical trial using a person's own stem cells to treat shoulder injuries, the American Medical Association is considering a request to add Current Procedural Terminology (CPT) codes so that other health care organizations can

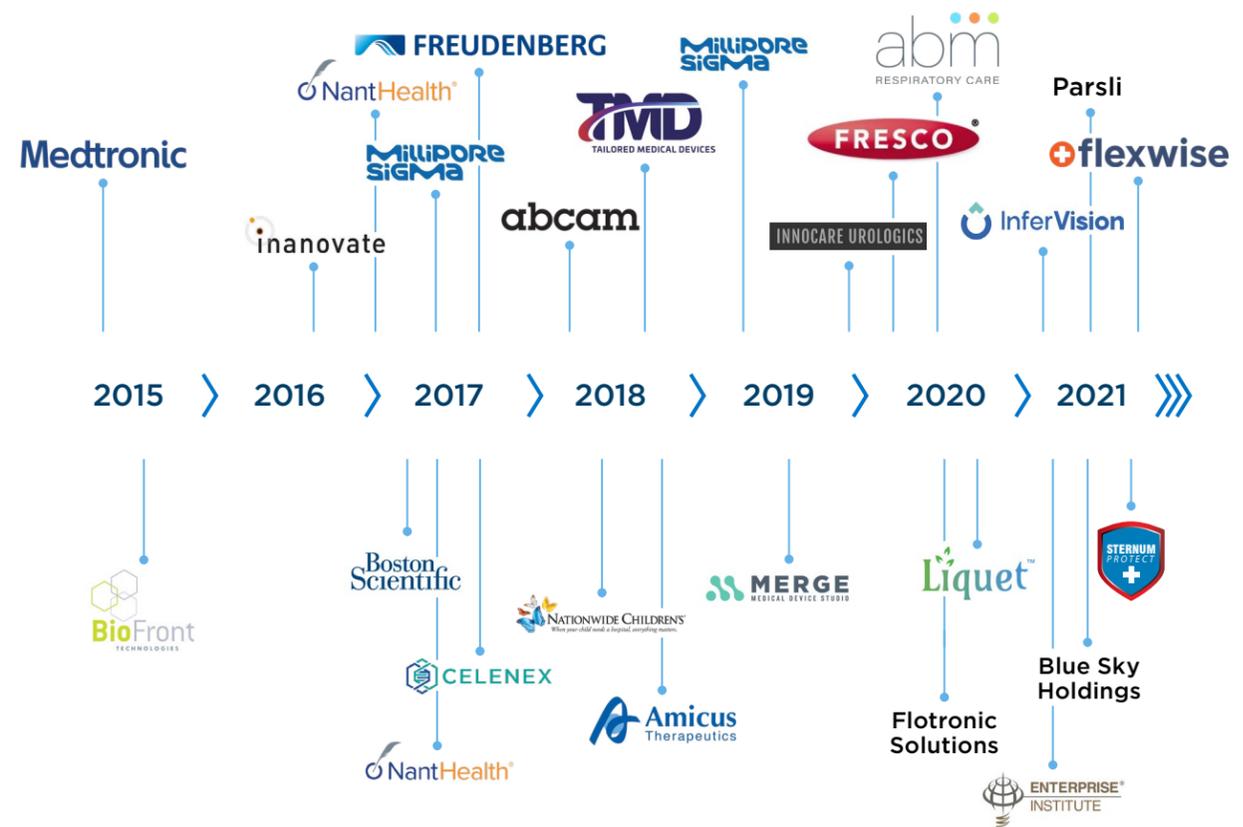
provide patients with improved mobility and reduced pain with the use of regenerative cells. Sanford Health orthopedic surgeon Mark Lundeen, MD, in Fargo is one of the principal investigators. Houston-based InGeneron, which created a system to separate the stem cells from blood vessel walls in fat tissue and deliver regenerative cells, sponsored Sanford's first trial as well as a larger study that continues.



MARK LUNDEEN, MD

OTHER PARTNERS

Below are some of the other respected companies Sanford Health has partnered with in innovation.



In addition to physical medical devices and tools, Sanford Health researchers and physicians are helping to develop software that helps both caregivers and patients.



SCOTT ENGUM, MD

SIMULATION CENTER SCHEDULER

Scott Engum, MD, a pediatric surgeon in Fargo, is working with Microsoft and Power Objects to develop simulation center software that schedules and tracks lifelike mannequin simulations used in medical training. In addition to Sanford Health care providers, the simulation center is regularly used by medical school students, residents in training, nursing school students, paramedics, emergency medical technicians and others which creates scheduling challenges. With few cost-effective options on the market, Engum went to Microsoft, which operates a large research and development center in Fargo.

EATING DISORDERS APP

Fargo researchers Scott Engel, PhD, Stephen Wonderlich, PhD, and Ross Crosby, PhD, have been using technology for years to understand the root causes of a variety of eating disorders, including anorexia nervosa, bulimia nervosa, obesity and the increasing problem of binge eating. By having patients use a personal device to record what's going on in their life at the time of an episode, the researchers gather more accurate data than if patients are asked to record it later. Engel, Wonderlich and Crosby first issued Palm Pilots to patients but now are working on an updated version of the software for smartphones called Real-Time Assessment In the Natural Environment (ReTAINE) 3.0.



SCOTT ENGEL, PHD
STEPHEN WONDERLICH, PHD
ROSS CROSBY, PHD

SOFTWARE

Perhaps no other field of technology holds as much promise as a prevention tool than augmented and artificial intelligence.

In 2021, Sanford Health's AI gained momentum with the introduction of several tools created by its Enterprise Data and Analytics (EDA) team to help patients and staff.

The World Health Organization also put out its first guidance on the use of AI in health care. Doug Nowak, vice president of data analytics, said Sanford Health already works to comply with all six principles outlined in the document.

AUGMENTED INTELLIGENCE

BEHAVIORAL HEALTH

Data scientist Clark Casarella, PhD, with input from provider champion psychologist Jeff Leichter, PhD, developed a model called Predicting Health Outcome in a Behavioral Health Outpatient Setting, or PHOBOS. It uses changes in a patient's medical history to try to predict their risk of developing three common behavioral health conditions: self-harm, psychosis-type events or chemical dependency.

DIABETES

Robert Menzie, MS, lead data scientist, came up with an AI algorithm that can determine the probability that someone has or might develop type 2 diabetes in the near future. It looks at the past five years of a patient's medical history and compares them to similar patients who were diagnosed with type 2 diabetes. The AI provides a risk score that the patient's personal care physician can then use to dig deeper. Scott Boyens, MD, a family physician who specializes in sports medicine, serves as provider champion for the project.

CANCER DETECTION

Three Bismarck physicians are collaborating with the startup company InferVision to create software to help spot cancer in CT scans. Brothers John Miller, MD, and Andrew Miller, MD, and fellow radiologist Joshua Rampton, MD, say digital imaging creates thousands of images, so they might miss a lesion that the AI would flag as a possible tumor. Those flagged areas are then further investigated for signs of cancer.



JOHN MILLER, MD / ANDREW MILLER, MD / JOSH RAMPTON, MD

BREAST CANCER

After seeing several younger women diagnosed with breast cancer, Chris Johansen, MD, and Laurie Kruse, MS, BSN, from the Edith Sanford Breast Cancer worked with advanced business intelligence analyst Austin Amdahl, MS, to look for an AI solution. They created an algorithm that looks through medical records for clues about family history. When a woman is identified as being at high risk for breast cancer, the team reaches out to her primary care physician and coordinates a visit, which can result in a screening before the age of 40.

SLEEP APNEA

Business intelligence analyst Max Weaver developed a tool that scans medical records for dozens of factors that could indicate whether a patient suffers from obstructive sleep apnea, which afflicts 1 out of 5 Americans and contributes to a host of health issues. This tool gives a patient's primary care physician more information to help determine if a sleep test should be ordered. The project champion, Kevin Faber, MD, chairman and medical director of sleep medicine in Fargo, said it's a powerful way to reduce unneeded testing, maximize the physicians' time and help patients who are otherwise unaware they have the condition.

COVID-19 RESPONSE

Sanford Health's investment in a data analytics team around 2015 also paid off during the pandemic. This centralized team of analysts and developers created models that helped determine how many patients might need to be hospitalized, be put on ventilators or require intensive care treatment. It also helped leaders know how much personal protective equipment the system would need and helped with managing staff levels.

When the Sanford Medical Center Fargo opened in 2017, it was equipped with numerous innovations that made it one of the most advanced hospitals in the region.

Sanford Health built on that foundation in 2019 when it opened the Innovation Unit on the eighth floor of SMCF, one of the only departments in the country to incorporate patient care innovations that may be applied to a broader patient population. The goal of the Innovation Unit is to improve patient and staff experience and outcomes, reduce waste and increase efficiencies by evaluating new ideas.

In 2021, the unit expanded to 32 beds to allow it to help more patients through these creative projects. [↗](#)

Hourly Patient Care for 08 B				Staff on 08 AB		On Time Rounds	
Last Patient Refresh: 3/17/2021 10:07:09 AM				Badge not reading? Check your badge status Here		52%	
Last RTLS Refresh: 3/17/2021 1:36:07 PM						Avg Minutes Between	
Round #	Patient Initials	Rounding Needed	Rounded Past Due	Not in Room	Name	104	Overdue Avg
Room		Last Rounded	Rounded by	On Time/Complete		117.0	
817	VC	9 min ago	Alice A	3/6	Nicole Angst		
818	DP	8 min ago	Alice A	2/4	Alice Anunda		
819	MS	25 min ago		3/6	Caitlin Eckhart		
820	TJ	15 min ago	Mackenzie O	2/4	Carli Jassop		
821	MS	14 min ago	Mackenzie O	2/4	Carlie Haeffner		
822				1/3	Emily Lund		
823	AL	74 min ago	Carli J	1/2	Heather Perez		
824	SM	46 min ago	Lorelei R	0/1	Heidi Marchant		
825	JK	74 min ago	Bethlehem S	1/4	Jeremy Rector		
826	TT	28 min ago	Desiree W	2/4	Jordan Lindenberg		
827	KK	49 min ago	Lorelei R	4/6	Lorelei Robinson		
828	EK	16 min ago	Desiree W	1/3	Madison Delbert		
829	CH	36 min ago	Desiree W	0/3	Mamasu Kollie		
830	BS	18 min ago	Mackenzie O	2/4	Melissa Kroppeng		
831	DR	36 min ago	Clarivel D	0/3	Merideth Bell		
832	MW	15 min ago	Lorelei R	3/5	Nicoleta Matei-bucur		

CARE DASHBOARD

One of the top ideas hatched in the unit so far came from Heather Perez, MSN, RN-BC, a nursing practice specialist who looks for ways to use technology to improve patient care and reduce some of the burden on nurses. She came up with an electronic rounding dashboard [↗](#) that displays when each patient had their last hourly visit, or care round, from a nurse. Already the device has improved patient care. The innovations team is exploring companies to partner with for further development.

BEDSIDE TABLE

A nurse in the innovation unit, clinical care leader Maria Diepolder, BSN, RN, came up with a way to maximize workspace without impeding patient space. Her solution is a small table that clips onto a bed or intravenous pole and provides a portable space for nurses to set up needed supplies for patient care. She's working with the innovation and commercialization team to develop prototypes.

MARIA DIEPOLDER, RN



SIX CLICKS

This physical therapy-based project allows for collaboration between the unit nurses and PT, standardizing how patient mobility is assessed and integrated into their plan of care.

ELECTRONIC WHITEBOARD

These electronic displays replace traditional whiteboards in each patient's room. The boards automatically update based on care team documentation in the patient's chart, providing the patient and their family with a real-time overview of their stay. It includes the care team's names for that shift, the patient's care plan and other details. The goal is to increase patient and family communication and address patient safety concerns.



HUDDLE BOARD

Another idea that was tested in the innovation unit and spread throughout the Fargo region is a huddle board in the nurses' station. It provides a visual overview of patient safety concerns and tracks safety metrics.

INNOVATION UNIT

One of the unique aspects of Sanford Health as a health care organization is its commitment to research tied closely to the clinical setting.

We employ some of the best minds in science and are committed to continually innovating new treatments that help our patients.

LIFE SCIENCES (RESEARCH)



PILAR DE LA PUENTE, PhD

NERVE-WRECKING CANCER RESEARCH

Most cancer treatments focus on killing cells. While this does attack cancer cells, it also damages healthy cells. Researcher Paola Vermeer, PhD, is taking a unique approach to slowing the growth of cancer that instead focuses on disrupting the nerves connected to the tumors. She's currently in the early stages of the research but is getting attention nationally because of its promise.

NEONATAL DRUG SAFETY TESTING

Michelle Baack, MD, Tyler Gandy and Pilar de la Puente, PhD, partnered to invent a precision-based drug safety testing platform for pregnant women and newborns. The platform uses stem cells isolated from the umbilical cord and cultured on a 3D cord blood scaffold to analyze the effect of a medication on developing cells. Most pharmaceuticals have an unknown safety profile for potential effects on fetal and newborn health; this screening technology helps establish safety for use in pregnant women and newborns.

PERSONALIZED CANCER TREATMENT

Pilar de la Puente, PhD, also has created a technology to allow precision-based drug testing to determine treatment efficacy for cancer patients. Cancer cells isolated from a patient's biopsy can be cultured outside of the body inside a patient-derived 3D plasma scaffold, with a wide range of treatments applied to the cells. The results of this testing could be useful in determining the most successful treatment regimen on a personalized basis.

BATTEN DISEASE

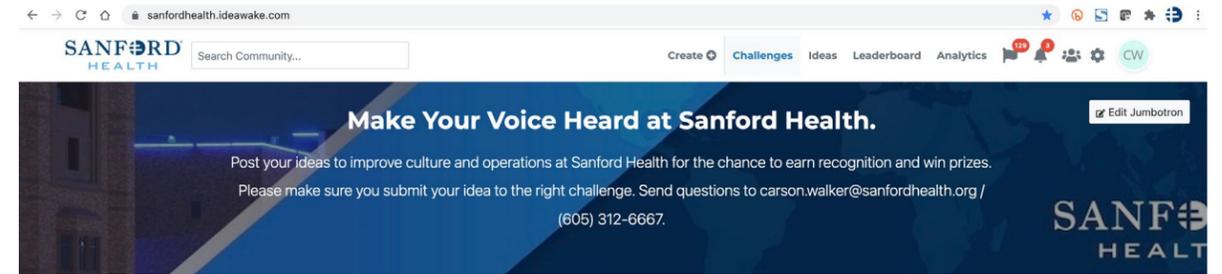
Batten disease, a family of rare neurological genetic disorders, is universally fatal to those born with it. Jill Weimer, PhD, has discovered that several small molecules may be useful in improving neurological cell function and disease symptoms for Batten disease patients. The therapeutics discovered by Dr. Weimer could be used in conjunction with these to improve outcomes for those suffering from Batten disease.



JILL WEIMER, PhD

One of the tools the innovation and commercialization team uses to collect ideas is the Ideawake crowdsourcing site.

Because it's web-based and approved for single sign-on, all Sanford Health and Good Samaritan Society employees can safely and easily engage with it through their smartphone, tablet or any computer on or off the network. [↗](#)



The Ideawake platform uses features for collaboration, such as voting on submissions, comments and “likes.” These help to increase user engagement in the idea challenge, and participants can be further incentivized with prizes in some cases. Challenges can be large or small — from a team or department to the entire organization.

The four regional Sanford Improvement Symposiums made their 2020 events virtual using Ideawake, and the Sioux Falls symposium used it again in 2021. The other regions paused their events because of the pandemic, which also limited use of the site, though several clinical challenges are in the works. And the innovation unit uses Ideawake to receive, evaluate and manage ideas submitted by nurses, physicians, leaders and support staff from all regions.

IDEA CHALLENGES

ENGAGE WITH THE TEAM

**If you're a Sanford Health nurse,
provider, researcher or other employee
and have an invention idea, problem
to be solved or potential innovation,
engage with the team:**



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MODIFIED LIMBS
TO BE ABLE
TO PERFORM
ENDO DEBRIDATION

COVERS SELF
EXPANDED STENTS

BALLOON
INFLATION
CORE

COMPLIANT
OCCUSION
BALLOON

DRUG
INFUSION
CORE

DRUG
DELIVERY
PORT

COMPLIANT
FURTED
BALLOON

OPTIMAL
LYRIC
CATHETER
TO
CENTRAL
PORT OCCUPY

LYRIC
INFUSION
PORT TO
CENTRAL PORT OCCUPY

WIRE COIL

DIA.

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