



Sanford Health
Commercialization
2020 Annual Report



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About us

Sanford Health established its commercialization team in 2008 to help physicians, researchers and other employees make their invention ideas commercially available. The technologies developed here may benefit patients, strengthen the organization's reputation as a global leader in care innovation, support the growth and development of the communities we serve and drive revenue generation. In 2020, the team focused on improving and standardizing the disclosure-to-commercialization process, which resulted in increasing inventor engagement, invention quality and invention production. Over the past 12 years the quantity and quality of invention ideas, licenses and managed technology have grown immensely, and we anticipate that growth to continue in 2021 and beyond. The following annual report highlights some of the major accomplishments from 2020.



A message from our chief business development officer



The Sanford Health Commercialization Department strategically manages all intellectual property generated by employees.

By building partnerships with our innovators, entrepreneurs and industry experts, we help facilitate the technology transfer that improves the human condition.

It is exciting, meaningful work. The creative spirit of Sanford Health staffers never ceases to amaze me, along with the commitment to our mission.

I believe our success starts with culture. And early on I see a culture of innovation, curiosity and continuous learning that is unique and can propel us forward. It's buoyed by ensuring all Sanford Health team members have the same opportunity to come forward with novel ideas that support the organization's ability to positively impact our patients, people and communities.

Thank you for taking a few moments to learn more about Sanford Health's commitment to innovation.

Sincerely,

Kent Lehr



Team changes

At the end of 2020, the commercialization team changed leaders with the retirement of long-time executive Kim Patrick. He created Sanford Health's legal department and served as chief legal officer and then chief business development officer. We thank Kim for his service to the commercialization team and Sanford Health and wish him all the best in his retirement.

Kim was succeeded by Kent Lehr, who came from UnityPoint Health where he most recently led organizational strategy and business development. Kent has a BA in biochemistry and molecular biology from Cornell College in Mount Vernon, Iowa, and a dual MBA and MHA from the University of Iowa.

The commercialization team also welcomed Eva Gut in 2020. She is working in an operations role, which includes management of patents, contracts and financials. She joined the team that works directly with inventors, which includes Tyler Remund, Katie Pohlson, Braden Bills, Rick Evans, Angela VandenHull and Amber Wolf.

Finally, Blayne Hagen, senior executive director in legal, joined the commercialization cabinet, which governs the commercialization activities of Sanford Health.

Commercialization cabinet members

Kent Lehr,
chief business
development officer

Kim Patrick,
chief business
development officer,
retired 2020

Luis Garcia,
president
of Sanford Clinic

David Pearce,
president of Innovation,
Research and World Clinic

Meghan Goldammer,
senior vice president
of quality and patient
experience

Bill Marlette,
chief financial
officer and treasurer

Sharon Hunt,
vice president
of Sanford Research
and Innovation

Dean Weber,
vice president
of supply chain

Blayne Hagen,
senior executive director,
legal

Quality and regulatory core

Sanford Health's commercialization team created a quality and regulatory core in 2020. This group, Katie Pohlson, Angela Vandenhull and Amber Wolf, provides guidance and insights to teams looking to commercialize an unapproved product. Its services, available to both internal and external clients, provide support in navigating the regulatory process and implementing quality systems. Additionally, they are experienced in database management, clinical study development and implementation, multi-site management, regulatory reporting and U.S. Food and Drug Administration approval.

This team is assisting Sanford Health's orthopedic stem cell program with its FDA application and Dr. Pat Kelly with his stent graft project.

For the stent graft project, Sanford Health received FDA approval in 2014 to run a physician-sponsored investigational device exemption, or PS-IDE. That allows physicians to study the early clinical performance of the device before it is used in a larger patient population. Rather than go it alone, Sanford Health, in collaboration with Medtronic, has developed a streamlined process that allows more surgeons to test the device and more patients to be treated with it. The six other health systems taking part in the study include New York University, Massachusetts General Hospital, University of South Florida, Vanderbilt University, The Johns Hopkins Hospital and The Christ Hospital. As the inceptive site, Sanford Health provides study development, templates, guidance and support to the collaborating sites.

"Had I not had the help of Pat (Kelly) and Katie (Pohlson), I would have never been able to have done any of these things on my own. It's a gigantic undertaking. And these guys understood what it took to get from point A to point B. And it would have taken me 10 times the amount of time that it took for us to do it had we not had their support and direction," said Dr. Geoffrey Answini, The Christ Hospital.

The quality and regulatory core has established a great working relationship with FDA, including co-authoring a template for an IDE application and IDE reporting. The team assisted internal and external partners with a variety of agency interactions in 2020, including pre-sub/pre-investigational new drug (IND) applications and meetings, regulatory reporting, interactive feedback responses and IDE/IND applications.

Express startup program

Startups (i.e., new businesses) that spin out of institutions like Sanford Health have become more common as big companies grow increasingly reluctant to finance early-stage discoveries. The resulting investment gap could threaten efforts to commercialize technologies developed internally. "Companies are moving further and further down the development path ... and that's creating this enlarged 'valley of death,'" said Stephen Susalka, CEO of the Association of University Technology Managers. New technologies need to be developed beyond the idea and napkin sketch phase by being prototyped and validated, sometimes to the point of generating clinical data, so that the innovation is de-risked and more likely to attract interest from established industry partners.

In response to this challenge, Sanford Health launched a startup program in 2020 that enables its employee inventors to commercialize intellectual property invented by the

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*Dr. Geoffrey Answini
The Christ Hospital*

employees through an employee-owned startup company. A key component of the startup program is Sanford Health's express license, through which the startup licenses the intellectual property that it will develop.

The organization studied similar programs at other institutions and concluded it was the best approach. The express license is designed to be fair both to the organization and the startup founders while also having terms that should be deemed "investable" by private equity. This standard agreement allows the startup to immediately work on building the company and the product rather than negotiating the license.

There are a number of requirements for a company to qualify for the Sanford Health express license. For example, an employee needs to be involved in the startup in some capacity. A business lead, who is responsible for the day-to-day operations of the business, is also required. The founders also need to create a business plan, and it needs to be approved by Sanford Health. Inventors already have started utilizing the startup program, and we expect to have more using it in the future.

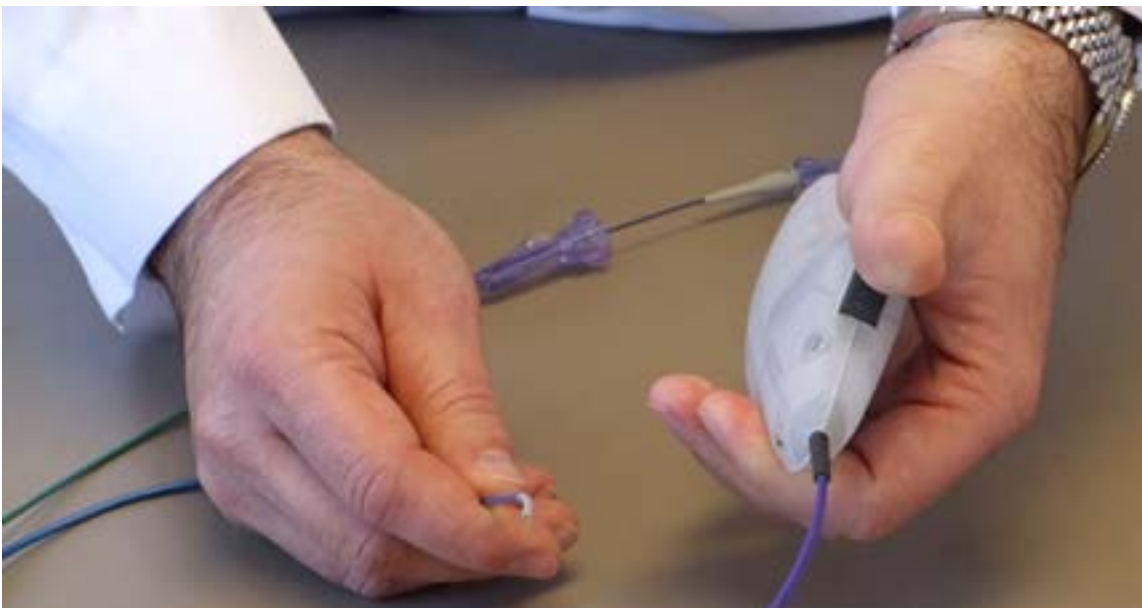
"Companies are moving further and further down the development path ... and that's creating this enlarged 'valley of death.' "

*Stephen Susalko,
CEO of the Association of
University Technology Managers*

Flotronic Solutions

Dr. Thomas Haldis, a Fargo interventional cardiologist, and Dr. Alexander Drofa, a Fargo neurosurgeon, utilized the new Sanford Health startup program and founded Flotronic Solutions LLC. The company was formed to develop the investigational Slide Guide Catheter technology for acute ischemic stroke intervention, which they invented.

When the two physicians came up with their initial ideas, they discussed starting their own company and talked to outside investors about the potential. Ultimately, they connected with the team at Sanford Health that helps physicians, researchers and others develop their intellectual property.



“They have a lot of experience, a lot of knowledge with regards to startups and technology and the patent process,” Haldis said. “Now is the time for Dr. Drofa and I to start this company and push the project through.”

“By starting the company, we are the ones completely responsible for the development of this product. But at the same time, we are very driven to succeed,” Drofa added.

The investigational Slide Guide Catheter combines two interventional catheters: a guide catheter to navigate near the occlusion, or blockage, and an intermediate catheter capable of suctioning out clots or deploying interventional devices such as a stentriever.

The current approach to repairing strokes requires the use of both of them with a bulky setup for the interventionalist. But the Slide Guide Catheter is intended to combine both in a system specifically designed for navigating challenging anatomy. It may allow more interventional cardiologists, interventional radiologists, vascular surgeons and other specialists to repair many untreated strokes.

The next step is to finalize and test the prototype in preparation to submit to the Food and Drug Administration.

Technology Readiness and Acceleration Center (TRAC)

The University of South Dakota collaborated with Sanford Health to launch the Technology Readiness Acceleration Center (TRAC) to train graduate students in entrepreneurship and technology development. TRAC is a new multi-institution technology commercialization center that supports entrepreneurship, startup creation and company growth. TRAC pairs USD graduate students with faculty inventors and trains them to be apprentices in the development and commercialization of novel technologies through education, innovation and entrepreneurship.

Students in the TRAC program will work with and be mentored by scientific entrepreneurs; learn how to combine research and development with commercialization; network and connect with industries; and have opportunities to own a business after TRAC program completion.

Students will also participate in workshops, the Three Minute Thesis Competition (3MT®), the Innovation Expo, the Governor’s Giant Vision Business Plan Competition, the South Dakota Biotech Annual Summit, and other events and competitions.

Graduate students can participate in the program for two years and are provided competitive stipends. They will spend the first year learning about intellectual property, entrepreneurship, technology development and laboratory skills development. Then they will select a technology owned by USD or Sanford Health and focus on preparing it for market application. The second year will be spent developing the technology, seeking further funding and either creating a startup company or forming partnerships with established industry partners. This program launched in August 2020.



Stent graft system

The Medtronic Valiant TAAA Stent Graft System is designed to help high-risk vascular disease patients who currently have limited clinical options. Sioux Falls vascular surgeon Dr. Pat Kelly invented the initial concept for the device that was licensed by Medtronic.

The device is designed to treat a thoracoabdominal aortic aneurysm, or TAAA. That is a complex condition that causes a dangerous bulging of the aorta extending from the chest down into the abdomen. The condition typically involves the branch arteries that supply blood to multiple internal organs. Left untreated, the aneurysm can rupture and cause sudden death.

The standard of care is complex open surgery, which is associated with a high rate of complications and mortality, and 40% of patients are not considered candidates for open surgical repair. Dr. Kelly's concept has the potential to open the door for more people to be treated with a minimally invasive approach.



Stent graft system

Dr. Kelly has continued to evolve the device over the years, including developing the second-generation version called the Unitary Manifold stent graft system. This device is

intended for aneurysms that extend up to the branch arteries but don't fully extend into the chest. It covers less of the aorta and hopefully will reduce the risk of devastating complications such as paraplegia. The Unitary device is currently offered only at Sanford Health as part of the physician-sponsored investigational device exemption.

The Journal of Vascular Surgery (JVS) published a paper in 2020 on the investigational Unitary system. Data from the first 44 patients show encouraging results in treating people who already have been treated for an aortic aneurysm.

JVS also published research results from Dr. Kelly's team that looked at age and thrombus, the buildup of clotted blood along the vessel wall, as an indicator for cardiac reserve. The results of this research may help identify which patients have a better chance at survival one year after treatment.

RightStep Pressure Reduction Sock

A company based in Barcelona, Spain, licensed and will begin manufacturing and selling the RightStep™ Pressure-Reduction Sock, which Dr. Pat Kelly invented. The company manufactures and sells podiatric, foot care and sports-related product lines in the European Union and will utilize a network of partners and distributors to sell the product in other markets, including the United States. The COVID-19 pandemic slowed the rollout, but the device should be available to its first patients in 2021.

The RightStep™ sock addresses a serious problem. There are 2.5 million hospital-acquired pressure injuries in the U.S. every year. This impacts approximately 3.5-4.5% of all U.S. inpatient hospital stays. The estimated total treatment cost is up to \$10 billion per year or up to \$20,000 per patient to treat. An estimated 60,000 patient deaths and more than 17,000 lawsuits each year are attributed to pressure injuries, second only to wrongful death.

Hospitals, departments and individual physicians employ numerous methods to prevent these lower extremity injuries. Among them are foam dressings, border dressings, heel pillows, heel boots and mobility boots. These all have their inherent flaws with inadequate pressure reduction, increasing friction and shear, and lack of mobility.

The RightStep™ Pressure-Reduction Sock is a medical garment worn on the foot and lower leg for pressure reduction during prolonged bed rest yet allows for walking. It has strategically placed gel pads to minimize pressure over the bony prominences of the foot, reducing the likelihood of tissue damage while keeping the patient independent and ambulatory.

For patients, it reduces pressure and helps reduce friction and shear, which lowers the rates of ulcers and blisters. For health systems, it improves patient/staff satisfaction, which reduces costs and guards against loss of federal compensation.

RIGHTSTEP

PRESSURE REDUCTION GEL SOCK

MOBILITY
Patients can remain independent and ambulatory while wearing the sock

EASE OF USE
Simple and effortless application for staff and patients.

OFF-LOADING
Pressure reducing gel that also protects against friction and shear

PACKAGE CONTAINS ONE UNIT

○ SMALL ○ MEDIUM ● LARGE

| | | | |
|--------|-------|---------|-------|
| Men | n/a | 7-9 | 10-13 |
| Women | 5-8 | 6.5-9.5 | n/a |
| Europe | 35-39 | 39-42 | 42-47 |
| UK | 3-6 | 6-8 | 9-12 |

Hospital-acquired pressure injuries are classified as “Serious Reportable Events” and are factored into penalties and reduction in Medicare payments of up to 1%.

The RightStep™ sock has potential benefits for the following increased risk patient populations: post-surgical, rehab, long-term care, intensive care unit, wound centers, orthopedic, podiatry and emergency department.

This device also would be used on any increased risk patient population, including patients with vascular compromise, diabetes, compressive therapy, limited mobility and bed rest orders over two hours.

Research tools

Sanford Research has a robust bench research program that focuses on diabetes, cancer, rare diseases and behavior science. In the course of their work, researchers often create tools such as plasmids, antibodies and animal models that enable their scientific inquiry. When research using and describing these tools is published, it can drive interest from other scientists in the tools. Fulfilling requests to supply the reagents to other labs can become burdensome for a lab, so commercial vendors will license these from Sanford Health and sell them to interested researchers. This eases the burden on Sanford Research investigators and can also generate revenue for Sanford Health.

The organization currently has several research tools licensed out, including the four highlighted below.

An **anti-SUSD2 antibody** was created for use in detection of the SUSD2 (Sushi Domain Containing 2) protein. This antibody is useful in determining the level of the protein present in tumor tissue or cultured cancer cells by immunoprecipitation or flow cytometry assays. SUSD2 has been shown to have various cancer prognosis implications, depending on disease type, and is also present in the endothelial lining of blood vessels. The antibody was licensed non-exclusively to MilliporeSigma, a leading provider of research reagents and chemicals.

The **Bio-ID proximal protein identification system** is useful to define protein-protein interaction complexes. The protein of interest is labeled with a special tag. After the addition of biotinylation agents, all proteins bound in complex to the protein of interest can be isolated and identified. Identifying new complex proteins can provide additional therapeutic targets for a given cellular signaling pathway. The Bio-ID system was licensed non-exclusively to Biofront Technologies, a provider of research reagents and testing components.

A set of cell lines was created to model **HPV16+ tumor growth** in mouse models of head and neck cancer. Throat cells from C57/Bl6 mice were isolated and transformed with Human Papillomavirus type 16 viral oncogenes, as well as the Ras oncogene, to transform the normal epithelial cells to cancer cells. Implanted tumors from the transformed cells accurately recapitulate the response to treatment seen in human HPV-positive head and neck cancers, providing valuable data on treatment outcomes and protein effects in cancer patients. The cell lines were licensed non-exclusively to Applied Biological Materials, adding to its vast cell line catalog.

ReTAINE, a smartphone-enabled research data collection tool, was created to aid in eating disorder research. The software allows study participants to log episodes and experiences as they happen, reducing the recall burden for the patients and minimizing

unreported incidents. The ReTAIN tool is specifically designed to assist with eating disorder research and has been licensed non-exclusively to several universities to assist their investigators with behavior data collection.

Safety Foley Urinary Catheter

A modified catheter invented by Bismarck radiologist Dr. Bruce Gardner to reduce pullout injuries has been licensed by a company whose founder co-invented technologies for the angioplasty balloon and coronary stent. Dr. Gardner developed the investigational catheter after numerous attempts. It's designed to allow for the retention balloon inside a person's bladder to deflate nearly instantaneously when tension is applied to the external tubing.

InnoCare Urologics LLC has agreed to develop, manufacture and sell Dr. Gardner's device, the Safety Foley Urinary Catheter.

Millions of people use Foley catheters. Dislodgment usually occurs when someone is confused or because of discomfort. It can also happen when patients trip or step on the bag or hose and when transferring patients from one location to another, such as during surgery. Damage to the body can include blood in the urine, lacerations to mucous membranes, urethral disruption or obstruction that requires surgery, permanent urinary incontinence and even death. Bleeding from lacerations also allows bacteria to get in the bloodstream and increases the risk of infection. In women, damage may include a prolapse in which the bladder is pulled out of the body. In men, dislodgment can damage the prostate or penis and result in permanent erectile dysfunction. Dr. Gardner's Safety Foley Urinary Catheter was designed to minimize the risk of these events occurring.

InnoCare Urologics was founded by Leonard Pinchuk, who won the prestigious Russ Prize in 2019 for his invention of the angioplasty balloon. He has more than 40 years of experience working with medical devices, with 130 issued patents and 100 publications. He has also cofounded 10 companies.

New orthopedic surgeon using 3D printing

Orthopedic surgeon Dr. Nathan Skelley wasted no time contributing several invention ideas shortly after joining Sanford Health in 2020. It's evident that Dr. Skelley enjoys identifying problems in clinical care, followed by using his innovative mindset and skillset to find solutions to these problems. He even maintains an inventor's notebook.

Commercializing new medical innovations typically takes years to obtain market interest and requires de-risking the innovation in some meaningful way, so it is a huge testament to Dr. Skelley's commitment to innovation that Sanford Health's commercialization team has already received market interest in many of his innovations. For example, he has used his own background in 3D printing to rapidly design prototypes, test them in the cadaver lab and then iterate the design into a preferred embodiment. It has been a unique opportunity working with Dr. Skelley to go above and beyond the typical "napkin sketch" phase of an idea.



Dr. Bruce Gardner



Dr. Skelley completed his undergraduate education at Cornell University in New York and went to medical school at Johns Hopkins University in Maryland. After medical school, Dr. Skelley completed his surgical residency at Washington University in St. Louis and Barnes-Jewish Hospital. He then performed his sports medicine fellowship at Harvard Medical School and Massachusetts General Hospital.

While there, Dr. Skelley worked with the Boston Red Sox, the Boston Bruins and the New England Patriots. It was the 2016-17 season for the Pats, which ended with a 34-28 Super Bowl win for the team.

Dr. Skelley comes from a family of health care professionals. His grandfather was a surgeon, his father is an oncologist, and his mother is a retired cardiac nurse specialist who now writes books for children and young adults.

In addition to being an innovative surgeon, Dr. Skelley has several hobbies that keep him active. He has a black belt in Sho-Tae-Ryu, a form of karate, and his first job was teaching martial arts. He also enjoys sailing and scuba diving, and most recently took up ballroom dance.



\$9.3M
licensing revenue*

Overall

141

unique
inventors

221

invention
disclosures

346

patents and
applications
managed

2020

52

invention
disclosures

18

patents
issued

6

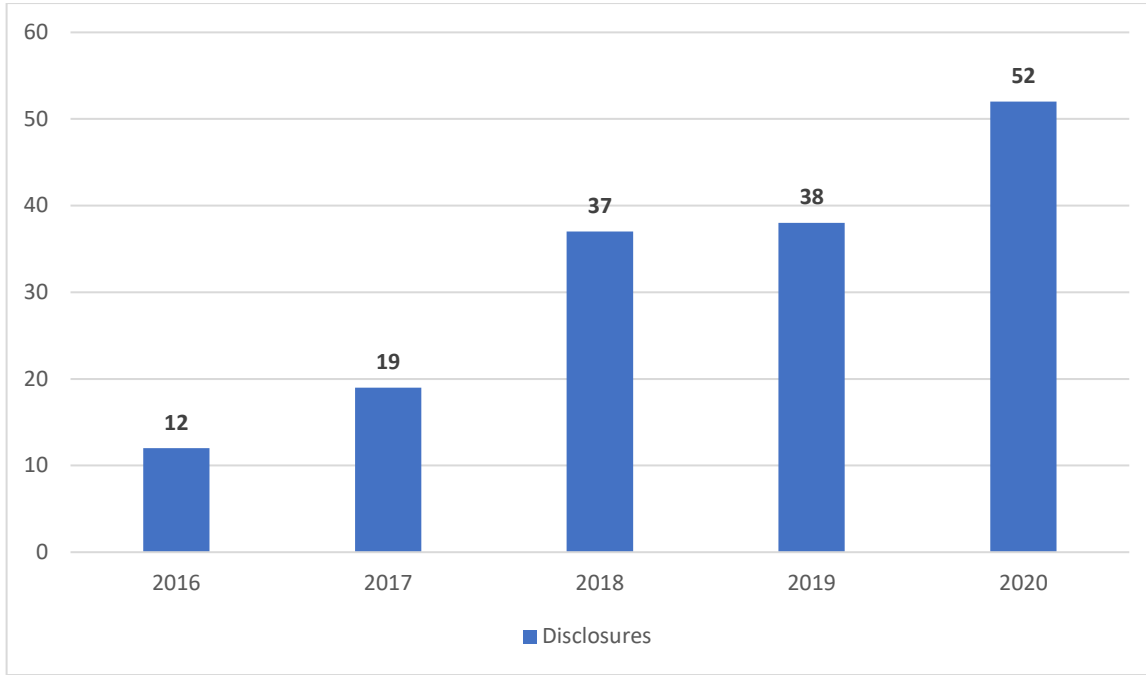
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1

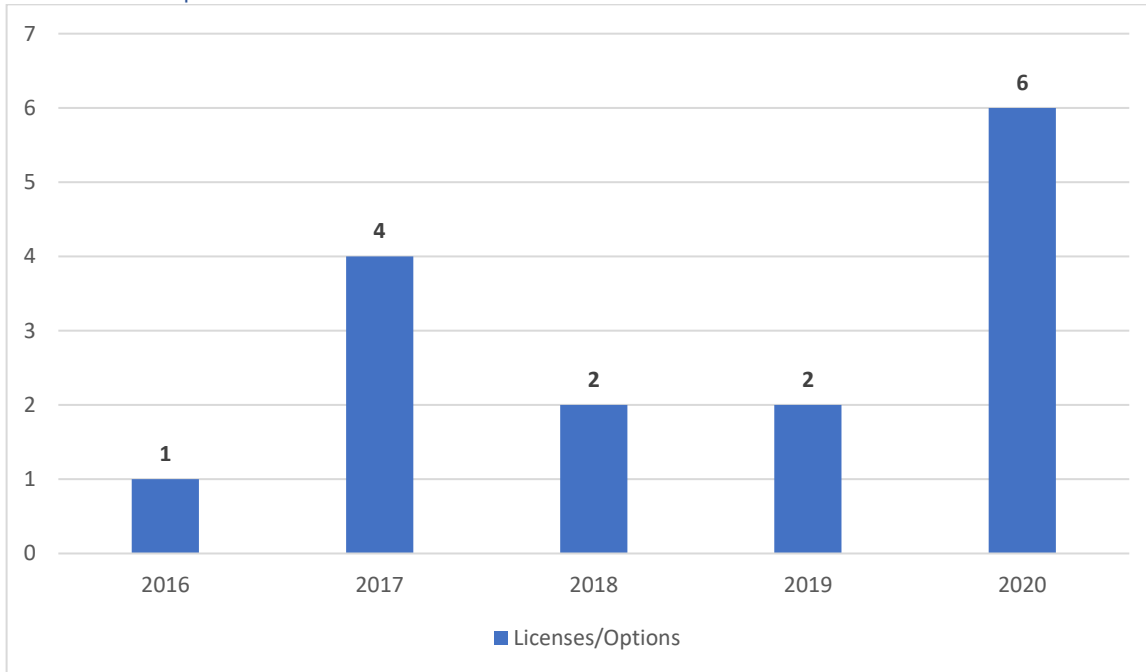
startup
formed

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

Disclosures Trend



Licenses / Options Trend



Invention disclosures to date by type

Since the department's inception, 221 invention ideas have been disclosed to the commercialization team.

Nearly half of the ideas have come from the Fargo region. Just over a quarter are from Sioux Falls, followed by Research, Enterprise Data and Analytics, Bismarck, Bemidji, Imagenetics, Technology Solutions (IT) and Finance.

Here's a breakdown by category.

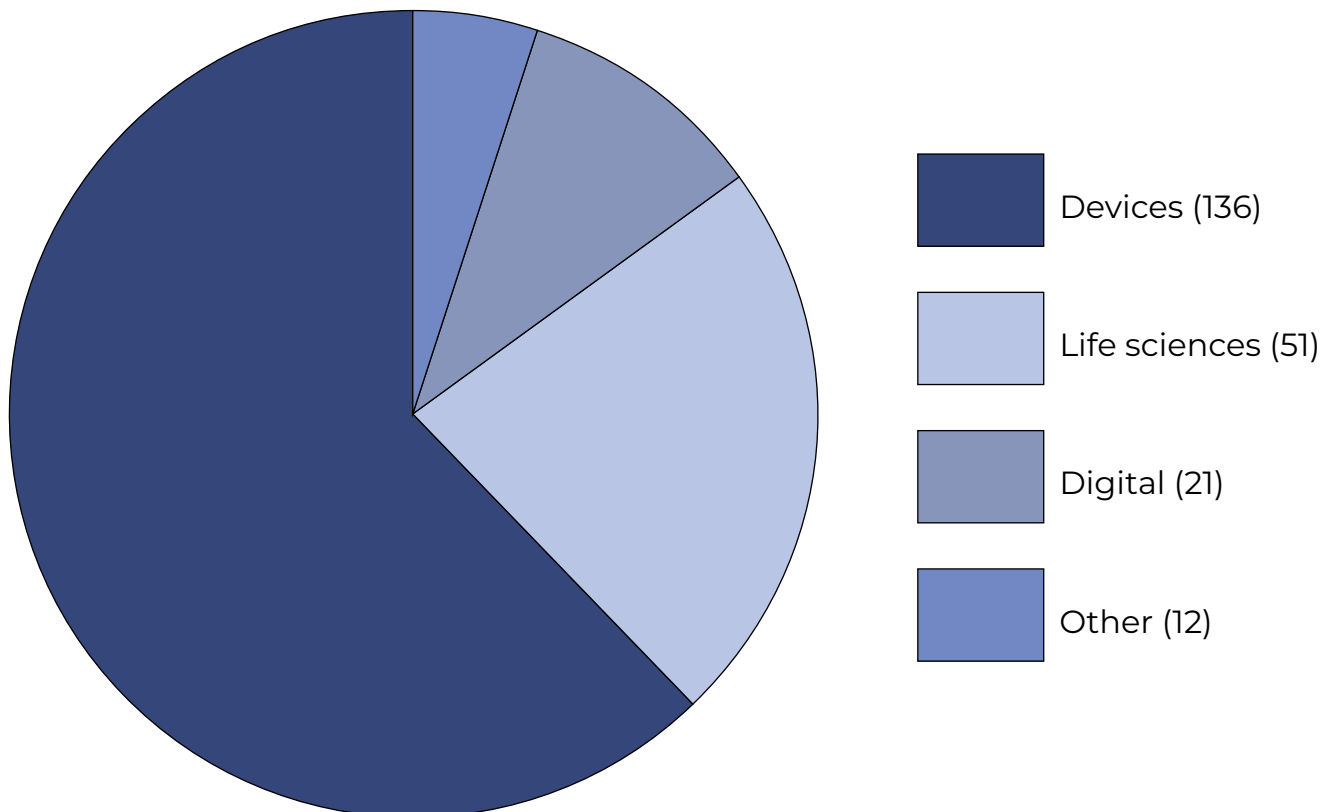
Life science: Derived from the research bench, including diagnostic assays, research reagents and therapeutics.

Device: Intended to be used in the care of patients, including surgical implants and treatment devices for the treatment or prevention of disease in patients.

Digital: Utilizes software, information technology, data science and artificial intelligence, including image analysis and patient identification programs to improve treatment or care of patients.

Other: Anything that does not fit into the other three categories.

Invention disclosures to date





In 2020, 52 invention ideas were disclosed. They are grouped by invention type below along with the inventor(s) and department/location of the employee(s).

Digital

1. Intra-luminal Flow Modeling and Device Positioning Software (Fargo)
2. Mobile Software for Medication/Pharmaceuticals Management, Verification (Fargo)
3. AI /Software System for Rib Fracture Intervention Decision Making (Fargo)
4. Tremor Detection Device and Software (Fargo)
5. Pregnancy Contractions Monitor (Fargo)
6. Sepsis Screening Tool (Bemidji)
7. Patient Transfer Software (Fargo)
8. Workforce Optimization and Forecasting (EDA)
9. ReTAINE (Research)

10. Type 2 Diabetes Prediction Model (EDA)
11. Sanford Chatbot – Lainey (Technology Solutions)

Device

1. Foley Bag Modification (Fargo)
2. Wheelchair or Stroller Runners (Fargo)
3. Disposable Walkie Talkies (Fargo)
4. Aerosol Ventilation Hood (Fargo)
5. Weighted Brain-Break Cap (Fargo)
6. Flexor Digitorum Tendon Cutter (Fargo)
7. Newborn X-Ray Imaging Pedestal (Fargo)
8. Straight Blade Artery Forceps (Fargo)
9. Ear Cerumen Remover Attachment for Otoscope (Fargo)
10. S-Shaped Dorsal Slit Forceps (Fargo)
11. Epistaxis Device (Fargo)
12. T-Track Double Lumen Tube (Bismarck)
13. Mask Adapter for End Tidal CO2 Tubing (Bismarck)
14. Telescopic Extrema (Sioux Falls)
15. PICC-Assist (Sioux Falls)
16. Pediatric Derotate Bone Plates (Sioux Falls)
17. Ocular Shield for Facilitating Generation of Visual Evoked Potentials (Sioux Falls)
18. Closed Capture Tissue Harvester (Sioux Falls)
19. Face Shield (Sioux Falls)
20. Flexible C-Shaped Slotted Cannula (Sioux Falls)
21. Advanced Handgrip Dynamometer (Fargo)
22. Arthroscopy Balloon (Sioux Falls)
23. Arthroscope Holder (Sioux Falls)
24. Sternum Project (Sioux Falls)
25. Knee Extension Device (Sioux Falls)

26. Port-A-Cath with Magnetic Localizer (Aberdeen)
27. Love My Feelings (Bemidji)
28. Rapid Field Tourniquet (Sioux Falls)
29. Iliac Crest Fixation (Fargo)
30. Ultrasonic Bone Cutting for Decompression (Fargo)
31. Carbon Fiber Pedicle Screw (Fargo)
32. Feeding Tube Bandage (Fargo)
33. Oxygen Flow Controlled with a Pulse Oximetry Sensor (Bemidji)

Life science

1. Soap with 20 Second Time Indicator (Fargo)
2. Antiseptic Foam for Abscesses (Fargo)
3. Cancer-Derived Small Extracellular Vesicles Promote Nerve Recruitment and Treatment Resistance in Ovarian Cancer (Research)
4. Modulators of Lysosomal Function (Research)
5. NTPDase 3 CAR-Treg Cellular Therapeutics (Research)
6. Telehealth Blood Test (Finance)

Other

1. Sewer Vent Stack (Fargo)
2. Mobile Shower Head Apparatus for Decontamination Showers (Fargo)



About us

If you are a Sanford Health employee and have an invention idea, contact the Sanford Health Commercialization / Innovations Department at the Stevens Center in Sioux Falls.

Email: innovations@sanfordhealth.org

Mail / Internal:

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900 E 54th St N
Sioux Falls, SD 57104

Learn more: sanfordhealthinnovations.org

Read inventor profiles and industry news: news.sanfordhealth.org/category/innovations

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