ON THE COVER

An expanded view of the diagrams submitted by Dr. Robert Jarvik, MD, for his patent of “Total artificial hearts and circulatory assist devices, including left ventricular assist devices” first developed at the University of Utah in the 1970’s.
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SUMMARY

The Center for Medical Innovation provides University of Utah students, faculty, staff, and the local entrepreneurial community with a centralized ecosystem of concept-to-prototype engineering resources, regulatory expertise, and entrepreneurial guidance coupled with experiential learning and immersive opportunities to discover and develop innovative, next-generation medical devices.

This report highlights many of the accomplishments of the Center for Medical Innovation throughout the 2022 fiscal year, in pursuit of its organizational mission.

To learn more, collaborate, or get involved, contact us at cmi@utah.edu.
AN ECOSYSTEM OF INNOVATION

PIVOT CENTER

SPENCER FOX ECCLES SCHOOL OF MEDICINE

S.J. QUINNEY COLLEGE OF LAW

CENTER FOR MEDICAL INNOVATION

COLLEGE OF ENGINEERING

DAVID ECCLES SCHOOL OF BUSINESS

LASSONDE ENTREPRENEUR INSTITUTE
The Gary L. Crocker Prototyping and Design Lab provides prototyping equipment and engineering services to students, faculty, staff, clinicians, and community partners to help build the next generation of medical devices.

A wide array of fabrication tools and workspaces enable proof-of-concept prototyping, as well as low-volume, end-use production parts. The lab provides support to a variety of research groups on-campus, including the University of Utah Hospitals & Clinics, the College of Engineering, and the Spencer Fox Eccles School of Medicine, among many others.

20+
ON CAMPUS RESEARCH & DEVELOPMENT PARTNERS

1,000+
3D PRINTED PARTS FY’22
ABOVE
Disposable support structures are removed from a 3D printed face mask prototype while being cleaned in a custom-built wash station designed to collect isopropyl alcohol.

LEFT
Robert Falconer, first year biomedical engineering PhD student, examines a surgical training device at the Crocker Lab.

RIGHT
Dr. Bryan McRae, MD, assembles a filtration system built by CMI for COVID-19 testing during the Fall 2021 return to campus.

LEFT
Marina Garcia Guijarro, Engineering Fellow at the Crocker Lab, applies silicone to 3D printed sinus cavity models, to be used for training tools among ENT residents.

ABOVE
Marina Garcia Guijarro, Engineering Fellow at the Crocker Lab, applies silicone to 3D printed sinus cavity models, to be used for training tools among ENT residents.
CMI is developing a novel, non-invasive monitoring system to determine a patient’s hemoglobin levels and quickly evaluate the likelihood and type of anemia. This enables faster results without a blood test, giving clinicians an opportunity to prescribe the appropriate anemia treatments to patients sooner.

Designed for low-resource and rural settings, this device focuses on simple and reusable components to ensure widespread use and longevity.

In May of 2022, CMI Engineering Fellow and PhD student Amanda LeMatty traveled to the state of Gujarat, India, to conduct two weeks of initial field testing of the device at a local hospital.

With hundreds of data points collected, the CMI team will now begin analyzing the data to refine the device for further development.
A continuation of the Center for Medical Innovation's response to the COVID-19 pandemic, the “U-Cover” project was awarded a $1.3 million collaborative research and development grant to design and fabricate an effective aerosol containment system for patients at risk of spreading an infectious disease.

Project partners:
» Rocky Mountain Center for Occupational and Environmental Health
» Division of Family and Preventative Medicine
» Dept. of Mechanical Engineering
» U.S. Dept. of Defense

As a better way to manage inventory and ensure each device is providing adequate protection to the wearer, the CMI engineering team partnered with University of Utah Hospital to design and manufacture custom mounts to allow RFID-enabled tracking tags on Powered Air Purifying Respirator (PAPR) systems.
EXPERIENTIAL LEARNING

STUDENT FELLOWSHIPS AT CMI

Educational programs at the Center for Medical Innovation combine the brightest minds from the University of Utah to constantly expand horizons and continue a legacy of pioneering medical innovation.

Offering a spectrum of opportunities, CMI experiential learning fellowships give students the chance to develop best-practices, refine business models, and understand what it takes to bring a transformative idea from concept to application in today’s health care ecosystem.

ENGINEERING LAB FELLOWS
Engineering Lab Fellows design and fabricate various device components and support fixtures for campus and industry partners under an ISO 13485 certified Quality Management System, preparing them for the rigors of working in the medical device industry.

HANSEN SUPPLY CHAIN VALUE ANALYSIS FELLOWSHIP
The Hansen Value Analysis Fellowship gives students the opportunity to participate in hands-on research and understand the complex decision-making process behind implementing new medical technologies in a health care system.

BENCH TO BEDSIDE STUDENT LEADERSHIP TEAM
B2B Student Leadership team members oversee the development of the annual Bench to Bedside competition, including student recruitment, event scheduling, curriculum development, and supporting student teams throughout the year.

REGULATORY AFFAIRS FELLOWS
The Regulatory Affairs Fellowship is a facilitated learning experience for students to understand the reality of the highly regulated medical device industry. Fellows learn how to do a full regulatory assessment, determine the appropriate regulatory pathways, and build a submission strategy for medical device products.

$115,000
FELLOWSHIP FUNDING
AWARDED FY’22

$1.7M
FELLOWSHIP FUNDING
AWARDED SINCE 2010
2021-2022 STUDENT FELLOWS AT CMI

TOM CARTER
ENGINEERING
Tom graduated in Jan 2022 with his bachelor’s in Mechanical Engineering, and began work at a local medical device manufacturer in Salt Lake City.

CHRISTOPHER CHRISTIANSEN
BENCH TO BEDSIDE
Chris is a second year medical student at the Spencer Fox Eccles School of Medicine.

JEEBIKA DAHAL
HANSEN SUPPLY CHAIN
Jabeeka graduated with a bachelor’s in Operations and Supply Chain Management in May 2022 from the David Eccles School of Business.

MARINA GARCIA GUIJARRO
ENGINEERING
Marina is a 3rd-year Biomedical Engineering student from Universidad Carlos III in Madrid, Spain, on a year-long exchange program to Utah.

JORDAN JOHNSON
BENCH TO BEDSIDE
Jordan is a first year medical student at the Spencer Fox Eccles School of Medicine.

JOHN MARTINEZ
HANSEN SUPPLY CHAIN
John will be graduating in Dec 2022 with his bachelor’s degree in Business Administration at the David Eccles School of Business.

AMANDA LEMATTY
ENGINEERING
Amanda is a first year PhD student in the Biomechanical Engineering program, focused on global health device innovation.

SAMANTHA VRANES
BENCH TO BEDSIDE
Samantha will be graduating in Dec 2022 with her master’s degree in Biomedical Engineering.
THE 12TH ANNUAL
BENCH TO BEDSIDE COMPETITION
APRIL 11, 2022
B2B 2022

BY THE NUMBERS

32
COMPETING TEAMS

$82,500
MILESTONE FUNDING AWARDED

154
STUDENT PARTICIPANTS

63
INDUSTRY AND CLINICAL MENTORS

16
PATENTS FILED

6
UTAH ACADEMIC INSTITUTIONS
LERC Medical developed the Dual Function Esophageal Probe, a device that measures oxygen saturation and temperature centrally via the esophagus, improving accuracy and reducing the number of wires in the surgical theatre.

uAir developed a mini albuterol inhaler for those with allergies and sports induced asthma. The device is highly portable (about the size of a key fob), readily accessible, and more affordable than other inhalers. The technology is based on the only miniature dose inhaler valve in the world.
## BENCH TO BEDSIDE 2022 AWARD WINNERS

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<tr>
<th>Category</th>
<th>Description</th>
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<tr>
<td><strong>Grand Prize Runner-Up</strong></td>
<td>ADMIX created a simple, low-cost buffering device, which utilizes existing anesthesia equipment which dentists can use to administer localized anesthetics more effectively.</td>
</tr>
<tr>
<td><strong>Best in Medicine</strong></td>
<td>The Lybb Tech Guardian Walker detects imminent falls using electronic sensors and automatically applies the walker brakes to prevent falls. The device could help prevent as many as 8 million fall injuries among seniors each year.</td>
</tr>
<tr>
<td><strong>Best in Business</strong></td>
<td>VAaN is a Virtual Anesthesia Assistant which includes voice-controlled activity recording for nurse anesthetists and patient overviews for attendings for improved integration of anesthesia equipment and reducing the burden of paperwork to the provider.</td>
</tr>
<tr>
<td><strong>Best in Engineering</strong></td>
<td>EaziStep is an alternative to crutches that works with the body’s natural biomechanics to improve energy-return and reduce pressure points. This hands-free design offers the potential to accelerate recovery and return patients to activity faster.</td>
</tr>
<tr>
<td><strong>Best in Digital Health</strong></td>
<td>Relay is a mobile app for team-based addiction recovery and self-improvement that helps recovering individuals connect with others. It eases the isolation often experienced by those struggling to overcome addictions and mental health challenges.</td>
</tr>
<tr>
<td><strong>Global Health Award</strong></td>
<td>Protean Medical provides surgeons in a wide range of specialties with a versatile light source at the surgical field level - all in an inexpensive, wireless, disposable package.</td>
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<td><strong>Eccles &amp; Marriott Libraries Award</strong></td>
<td>NeoTec has developed a vibration-dampening device to mitigate the risk of hemorrhaging in neonates during emergency transportation.</td>
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<tr>
<td><strong>Consumer’s Choice</strong></td>
<td>SaltTech has developed an improved pulse oximeter which more accurately assess oxygenations levels for individuals regardless of levels of skin pigmentation.</td>
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The Therapeutic Games and Apps Lab (The GApp Lab) is a collaborative effort between University of Utah Health and the Entertainment Arts and Engineering (EAE) Program to research and develop meaningful ways to introduce clinically validated, playful video games and virtual reality-based applications into hospitals, clinics, and at-home settings.

Each semester, approximately 30 students from the EAE master’s degree program join The GApp Lab to begin the process of video game design or continue facilitation of long-term clinical trials with University of Utah Health researchers, clinicians, and industry partners.

- **Color Me Healthy** offers pediatric patients a chance to record symptoms in a diary-style tablet app.
- **Neurogrow** invites players to care for a virtual garden. Routines are shown to treat geriatric depression.
- **Virtual Home Visit** gives College of Social Work students an opportunity to practice field visits in Virtual Reality.

**Members of the 2021-2022 GApp Lab Cohort**
Understanding the standards and regulations surrounding the development and distribution of medical devices is crucial to successful commercialization. To ensure success on what can be a highly regulated path, the Regulatory Affairs team at the Center for Medical Innovation provides students, clinicians, faculty-inventors, and other early-stage start-up groups from the University of Utah community with expertise and guidance with the following objectives:

» Help those with new devices plan strategically from design to market.
» Identify the regulatory requirements for medical and In Vitro Diagnostic (IVD) devices and provide advice and services for compliance.
» Prepare and assist clients in regulatory submissions, manufacturing compliance, quality system implementation, and other regulatory requirements for most Class I & Class II devices.

<table>
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<tr>
<th>REG. AFFAIRS FY’2022 HIGHLIGHTS</th>
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<tr>
<td><strong>3 510(K) SUBMISSIONS</strong></td>
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<tr>
<td>A 510(k) is a premarketing submission made by medical device companies to FDA to demonstrate that the device to be marketed is safe and effective, and substantially equivalent, to a previous legally marketed device.</td>
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<tr>
<td><strong>2 TECH FILES (CE MARKED)</strong></td>
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<tr>
<td>» The Tech File is a mandatory technical document device manufacturers submit to regulatory authorities in the European Union for approval to commercially distribute medical devices in the EU.</td>
</tr>
<tr>
<td>» It is similar to 510K submission, but a tech file is meant for EU regulatory agencies.</td>
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<tr>
<td><strong>ISO 13485:2016 CERTIFICATION</strong></td>
</tr>
<tr>
<td>» ISO 13485 is the medical device industry’s most widely used quality management standard for the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices intended for commercial distribution.</td>
</tr>
<tr>
<td>» CMI successfully passed a multi-day surveillance audit, ensuring ISO 13485 compliance.</td>
</tr>
<tr>
<td><strong>12 INDUSTRY CONSULTATIONS</strong></td>
</tr>
<tr>
<td>Offering Regulatory Affairs consultations to organizations outside the University of Utah reinforces CMI’s commitment to building the life sciences industry in our community.</td>
</tr>
</tbody>
</table>
Beginning as a student project during the 2011-2012 school year, the “FIT Catheter” project as it was known then would go on to win $9,000 in milestone funding at that year’s Bench to Bedside Competition.

The awards earned by the team that night turned out to be a sign of the future success Light Line would achieve in the years to follow.

Now officially known as Light Line Medical, Inc. is still based in Salt Lake City, Utah, and was established to develop a patented, non-invasive visible light platform to prevent catheter associated infections. The technology does not use harmful UV light, chemicals, or drugs that are resistant to antibiotics; the third leading cause of death worldwide.

Infection of invasive catheters has become one of the greatest causes of morbidity and sources of cost in medicine today. The alliance will focus on finalizing the development of a low cost, intuitive, effective infection prevention system utilizing a particular wavelength in the visible light spectrum generated by an LED laser and delivered through a specially treated fiber optic to deliver uniform light down the length of an indwelling catheter.

In July of 2022, Light Line announced it entered into a “know-how” License Agreement with Mayo Clinic to advance its visible light infection prevention system for off-the-shelf catheters. The collaboration will focus on the technology in peritoneal dialysis catheters, Foley (urinary) catheters, endotracheal tubes and vascular catheters.

Light Line plans to launch its peritoneal dialysis product in the U.S. in early 2024, followed by global launches of its dialysis product and other products in development.

To learn more, visit www.lightlinemedical.com

Currently, Light Line’s published international patent portfolio includes 23 issued patents and 16 pending patent applications, including the LIGHT LINE™ DIALYSIS device pictured above.
While earning his PhD at the University of Utah in 2012, Brandon Welch discovered a gap in the market: patient visits by video, specifically patients who did not need in-person visits but wanted to speak with their doctor.

“I looked for HIPAA compliant telemedicine solutions that were free and simple to use, and there was nothing,” he said. “I thought I’d just put the idea into the Bench to Bedside competition. I got a couple medical students and other graduate students to help build an initial prototype of the app, just kind of threw it together and went to the competition.”

“Doxy.me” as the project became known, went on to win $3,000 in the 2013 Bench to Bedside competition, taking home the Consumer’s Choice award – an early indicator of the growing desire for better telemedicine options.

Welch invested the prize money into an upgraded prototype, and went on to top ten finishes in the Utah Entrepreneur Challenge and Opportunity Quest competitions hosted by Lassonde Entrepreneur Institute. Doxy.me then joined the first cohort of startups in the Master of Business Creation (MBC) program in 2019-20 at the University of Utah’s David Eccles School of Business, spending nine months developing and growing their business with support from scholarships, mentors, and peers.

The company received more grants, including a Small Business Technology Transfer (STTR) grant from National Institutes of Health (NIH) for $225,000, to extend doxy.me into the clinical research market. Since founding in 2014, doxy.me has received more than $600,000 in grant funding to research telemedicine innovation.

To learn more, visit www.doxy.me
ORGANIZATION INFORMATION

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The Center for Medical Innovation is located on the lower level of the Spencer S. Eccles Health Sciences Library (EHSL), highlighted on the diagram above and to the right.

To reach the CMI Offices, enter EHSL on the main level, and take the central staircase to the lower level. All visitors are requested to check in at the CMI front desk upon arrival.

Paid visitor parking is available in the South Medical garage.