2015 ITHS Summer Fellowship Projects

1) Project: RainCity HeartLab- Better Measures of Heart Risk
   * **UW PI:** Jay Heinecke, UW Medicine
   * **Business Mentor:** Erik Nilsson
   * **CoMotion Technology Manager:** Lindsie Goss

   Current methods of assessing heart risk are inadequate. Cholesterol levels fail to predict 70% of 1st heart attacks in “low risk patients”. Conceived by physicians and realized by scientists, our company is poised to transform the way clinicians assess cardiovascular disease. RainCity HeartLab’s product is a diagnostic test for heart disease, termed CALLIS (Calibrated Lipoprotein Ion Separation), to be used by physicians to estimate the risk of future adverse cardiovascular disease (CVD) events such as heart attack. CALLIS evaluates the quantity and size of HDL particles (HDL-Q; the good form of cholesterol) as well as LDL particles (LDL-Q; the bad form of cholesterol).

   In collaboration with CoMotion, we are interested in identifying a summer intern that can work with RainCity HeartLab to help position the technology for spin-out from the UW:
   - Perform a market analysis to clarify our value proposition and strategic positions.
   - Identify, specify, and size introductory markets for this assay for non-clinical research use (such as drug development).
   - Outline a market penetration plan for the above identified markets, including phrasing and customer feedback from potential customers.

2) Project: TransCellular Therapeutics – Enzyme Replacement therapy for Barth Syndrome
   * **Principal Investigator:** Michael T. Chin, UW Medicine
   * **CoMotion Technology Manager:** Lindsie Goss

   We are developing an injectable biologic for treatment of Barth Syndrome. Mutations in the TAZ gene, and subsequent decreases in intracellular tafazzin levels, are associated with clinical disorders such as Barth Syndrome, which present with myopathies as well as neutrophil deficiencies. Although Barth’s Syndrome is rare, many more people are carriers for this X-linked disorder. Reduced levels of TAZ have also been observed in other forms of experimental heart failure and in clinical samples from patients with heart failure, raising the possibility that abnormalities in TAZ-dependent mitochondrial function may serve as a final common pathway for heart failure. The clinical manifestations of Barth Syndrome include muscular hypotonia, cardiomyopathy and neutropenia. At present, no effective therapy exists for affected individuals.

   Dr. Chin’s lab at UW has developed a recombinant TAZ reagent engineered for cellular uptake that shows efficacy as an enzyme replacement therapy in a preclinical model and is now covered by a non-provisional patent application. Dr. Chin founded TransCellular Therapeutics with the goal of commercializing this novel therapeutic by attracting investment, completing preclinical studies, preparing an Investigational New Drug application for FDA approval and performing a first in human trial. If all goes well, we hope to complete these milestones within the next 2 years.

   We seek a motivated MBA student to:
   1. Perform detailed market analysis to assess potential revenues
   2. Perform a detailed cost analysis for scale up and manufacturing
   3. Assist with developing a business plan and pitch for potential investors
   4. Perform background research on regulatory hurdles encountered by other enzyme replacement therapies that would assist with planning of the Investigational New Drug application.

3) Project: Center for Cancer Innovation- Tumor Crowd Modeling Platform
   * **Founding Team:** Tony Blau, Kimberly Burton, Brigham Mecham
   * **CoMotion Technology Manager:** Lindsie Goss

   The cost of cancer care in the US is expected to double by 2020 and no significant decline in death rates is projected. UW Medicine’s Center for Cancer Innovation’s (CCI) mission is to place the world’s knowledge, technology
and resources at the disposal of individual cancer patients (“all for one”), while learning from their experiences to add to our collective understanding about how cancer works for the benefit of future patients (“one for all”).

Over the past 15 months CCI has launched a series of “next generation” clinical trials; the Intensive Trials of Omics in Cancer (ITOMIC) and its Tumor Crowd Modeling Platform (TCMP). A clinical trial of high throughput drug screening for Acute Myeloid Leukemia (AML) is spinning off toward commercialization and is not described further here. Having established the feasibility of these programs, the next step in achieving CCI’s vision requires scale up.

We are requesting a highly motivated student interested in personal genomics & cancer care to help with the below:

1) Prepare a detailed competitive analysis.
2) Define the addressable market and understand the motivations of the different constituents: cancer patients, oncologists, researchers, biotech/pharma.
3) Outline various go-to-market strategies.
4) Suggest a sustainable funding model(s) that is not dependent on grants/donations.

4) Project: Improved Angle Prosthetic

*Principal Investigator: Murray Maitland, Department of Rehabilitation Medicine*
*CoMotion Technology Manager: Ryan Buckmaster*

On an average day, more than 230 people in the US will have a low limb amputation resulting in 623,000 Americans is currently living with major lower extremity amputation. However, even the most advanced current prosthetics fall far short of replacing the function of the lost limb. In particular current prosthetic feet are inadequate because they do not adequately adjust to sloped or rough ground resulting in lower mobility, frequent falls and significant discomfort for amputees. But researchers at UW have designed a novel prosthetic foot using a novel mechanical system that automatically adapts to rough ground while still being robust enough for everyday use and affordable.

A motivated and entrepreneurial Summer Fellow with an interest in commercializing patient driven technologies to work with an interdisciplinary team consisting of physical therapists, prosthetics, physicians, engineers, engineers and prosthesis users to:

1. Refine market size and develop strategy to address different segments and price points.
2. Develop profiles of potential partners and competitors including prices, units sold, sales history, growth rates and market entry strategies as well as acquisition and licensing activity in industry.
3. Develop detailed competitive matrix of prosthetic foot models on the market
4. Assist team in preparing commercialization grant applications such as LSDF and STTR programs.
5. Gross margin assessment. Analyze likely cost of goods and likely reimbursement cost to establish product margins.

5) Project: Smart Lenses: Intraocular sensor for glaucoma monitoring

*Project Lead at Smart Lenses: Dr. Nerea Alayo*
*Founding Team: Prof. Karl F. Bohringer, Prof. Tueng T. Shen, Dr. Nerea Alayo and Dr. Mike T. Khbeis*
*CoMotion Technology Manager: Forest I. Bohrer*

*Smart Lenses* is a new ocular biomedical devices start-up based in Seattle, WA. The seed idea of this solution arose five years ago with the collaboration of the Prof. Bohringer’s bioMEMS lab and Prof. Shen from the School of Medicine, both at University of Washington. The general goal of the company is to provide solutions to monitor parameter of our body in regions of difficult access, as the eyes. The first product of *Smart Lenses* is an Intraocular Pressure (IOP) sensor that allows the continuous monitoring and early detection of glaucoma. Glaucoma is the second cause of blindness in the world, affecting 60 million people worldwide. It is a painless and progressive lateral reduction of the sight due to the increase of the intraocular pressure, therefore most of the people don’t notice it until irreversible symptoms appear. For the accurate diagnosis of the disease daily IOP measurements are needed and current methods don’t provide this information. From the three million people having cataract surgery every year in US, a high percentage of them develop glaucoma after some time. During cataract surgery the human lens is replaced for an artificial lens using a well-
established procedure. The pressure sensor will be embedded in that artificial lens and implanted during the cataract surgery with no additional complication. We expect great interest from the big intraocular lenses manufacturers, such as Alcon or Abbott, to include our sensor in their lenses due to the low risk that it supposes comparing with the large revenues that are anticipated.

Join us in the exciting adventure of creating a start-up that will improve millions of people’s vision!

Smart Lenses wants to become the first company having a real solution to continuously monitor glaucoma and stand out on the field of smart implants. As important as design and test the sensor, is to perform a deep study of the business development. Smart Lenses is looking for a summer intern that would:
1. Develop a market research, vet the commercial opportunity behind our product development leads and evaluate the product targets business.
2. Perform a detailed reimbursement analysis of Smart Lenses’ technology and target portfolio, comparing with other glaucoma diagnosis and treatment options.
3. Based on the outcome of tasks 1 and 2, review and propose potential adjustments to our strategic positioning.

6) Project: Seattle Children’s Hospital, Learning & Simulation Center – Synchronous Mobile Audio-visual Recording Technology Cart (SMART-Cart)

Principal Investigator: Don Stephanian, Development & Design Manager, Seattle Children’s Hospital

Medical simulation is a rapidly growing methodology for training healthcare professionals through the use of cutting-edge technologies. Traditionally, large and costly simulation centers containing simulators, audio-visual recording and playback monitors, training labs, conference rooms, etc., are used. In this static setting, learners benefit significantly from the added perspective of video-enhanced debriefing.

In-Situ simulation, or simulation that is physically integrated into a clinical setting, substantially increases the level of realism for learners. The use of real-life work environment training is more applicable for building competence in teamwork, communication and medical management skills, which translates into improved patient outcomes. The ability to support learning with video-enhanced debriefing practices during in-situ simulation in necessary to maintain continuity to that of a fixed simulation center, but can be limited by capacity of the simulation technologist to quickly and easily record and playback video in the clinical environment. Reducing this impact on clinical time and space plays a major factor in the successful use of the in-situ simulation model.

In collaboration with Seattle Children’s Hospital, the Synchronous Mobile Audio-visual Recording Technology Cart (SMART-Cart) was developed. The SMART-Cart was developed using Lean principles to combat these unique challenges and meet the needs of our physician and nursing educators and learners.

The SMART-Cart is composed of a compact metal cart with integrated components; dual wide-angled pan-tilt-zoom cameras and remote lavaliere microphones, a 500 GB audio-video computer with two rear facing LED monitors, and a large front-facing LED monitor positioned for easy video playback and review. Inside the cart there is room to store and transport a pediatric mannequin, components, scenario library and supplies.

During a pilot-testing phase involving 75 in situ simulations with the capture of over 10 GB of audio-visual data, the SMART-Cart functioned extremely well with no technical issues encountered. In a time trial study, room setup and take
down speeds were significantly faster using the SMART-Cart as compared to traditional methods (set up: 3.5 min vs. 56.6 min; \( p = 0.003 \), take down: 3.1 min vs. 41.9 min; \( p = 0.002 \)). There is also a 50% reduction in the overall footprint of the simulation equipment and cameras in the available training space (SMART-Cart 8 sq. ft. vs. conventional 14 sq. ft.).

Based on this experience, the SMART-Cart provides a fast and reliable option to facilitate video-enhanced debriefing during in-situ simulation. The SMART-Cart appears superior to traditional methods of in-situ video recording and playback. The SMART-Cart could function as the stand-alone audio and video system in any fixed simulation center for a fraction of the cost of an installed video system. Potential uses include the SMART-Cart as a plug-in to the primary video system in a current or new fixed simulation center, and to conduct video-enhanced debriefing during in-situ simulation-based outreach at other facilities. Furthermore, SMART Cart is a low cost, high impact training option for any size facility interested in starting, or growing a simulation program.

With the successful completion, testing and integration of SMART Cart, new opportunities in the local and global industry have arisen, which warrant additional considerations. A second version drawing of SMART Cart has now been completed. A US Patent application was recently filed, which also includes Canada & Australia. In April 2014 SMART Cart won the international award for innovation at IPSSW, presented in Vienna. Over the past six months Children’s has hosted outside institutions interested in following in our simulation footsteps. In December 2014 we received a letter of commitment from a local hospital for the purchase of a SMART Cart. SCH simulation leadership team has indorsed moving forward with building additional SMART Cart’s for our institution. These modified versions of SMART Cart are aimed at accommodating adult size simulators for adult care facilities and the US military. In May 2015 SMART Cart will travel internationally to Canada to be used in two simulation workshops, which we anticipate will bring additional interest and buyers.

Link to demo video:
https://www.youtube.com/watch?v=edpdJ4AHuGY

Link to SCH Learning & Simulation Center web site:

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- Perform a market analysis to clarify our value proposition and strategic positions.
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- Outline a market penetration plan for the above identified markets, including phrasing and customer feedback from potential customers.

Principal Investigator:
- Don Stephanian, Development & Design Manager, Seattle Children’s Hospital

Contributing Investigators:
- Tom Pendergrass, MSPH, MD, Director of Medical Education
- Maureen Pound, Director of Graduate Medical Education Program
- Taylor Sawyer, DO, M.Ed, Neonatologist
- Douglas R. Thompson, MD, Director Pediatric Anesthesia Department Simulation
- Pam Christensen, MN, RN, Clinical Nurse Specialist Post Anesthesia Care Unit

We seek a motivated M.B.A. student to:
1. Perform detailed market analysis to assess potential revenues
2. Perform a detailed cost analysis for scale up and manufacturing
3. Assist with developing a business plan and pitch for potential investors and partners
4. Perform background research on regulatory requirements.
2015 WRF Summer Fellowship Projects

1) Project: A Blood-Based Food Allergy Test

Principal Investigator: Dr. Erik Wambre, Benaroya Research Institute

Thirty percent of Americans think they have a food allergy. In reality, less than 5% of adults and 8% of children suffer from food allergies. So an objective, accurate and less expensive food allergy test is needed.

Among currently used food allergy tests, skin prick tests, immunoassays (detecting antibodies in blood) and oral food challenges (OFC), OFC is the most definitive method for diagnosing food allergy, but this procedure is very expensive and can take upwards of 8 hours and requires dedicated facilities and specially trained personnel to perform appropriately.

Benaroya Research Institute at Virginia Mason has developed a novel blood-based test to diagnose food allergy. This test uses flow cytometry to identify, detect, and quantitate the frequency of a subtype of activated Th2 cells, named Th2A, in blood samples obtained from suspected food allergy patients. The presence of specific allergen activated Th2A cells in blood indicates the patient’s allergic condition to the specific food. The test is fast, inexpensive, accurate, and has no harmful reactions to patients compared to OFC. Additionally, the test can be used to diagnose non-food types of allergy.

We are currently seeking MBA students with emphasis on financial and operational planning to evaluate this project as a potential startup opportunity. If you are interested or have further questions about this technology, please contact us at bizdev@benaroyaresearch.org.

Tasks:

a. Perform market research on the opportunity for the test as an alternative to OFC. Segment the market in terms of potential food allergies and geographies.

b. Assess the current and projected competitive tests relative to the OFC both as a diagnostic test.

c. Identify and/or develop an economic model quantifying the potential value of the blood-based food allergy test.

2) Project: LearnTogether: Peer-to-Peer Learning and Networking for Professionals

Project Lead: Bob Boiko, UW Senior Lecturer

C4C Technology Manager: Gail Dykstra

LearnTogether is a learning management system for professional training.

It combines cutting edge learning techniques with sophisticated social networking to let a group of related professionals learn together.

More experienced professionals upload their best work product. We turn their best work into learning materials and level-up challenges. Less experienced professionals study the expert’s work then master a challenge to prove to the expert they are ready to move to the next professional level on a particular skill. One person can be a learner on some skills and an expert on others. LearnTogether creates an organic mentoring and peer network through which knowledge can travel and personal relationships can form and flourish.

Currently LearnTogether is:

- Designed for department managers with a staff of between 50 and 500 professionals.
- Has a $26b and growing market in the leadership training market
- Has preliminary market and competitive analyses
- In the first year of a 2 year incubation within UW before spinning out as a start-up
- Is funded through the first year a UW GAP fund grant, and generous support from the UW Information School and Costco Inc.
- Has a team of 10 programmers, designers, and content creators
- Will release a first test version in fall for testing and evaluation at Costco.
Please help us complete our incubation and begin to seek external capital. As we complete version 1, we need assistance.

Tasks:

- Gather voice of customer to assess brand-recognition (vs similar programs/products)
- Identify institutional customer decision points/process & map current LearnTogether offerings
- Undertake market research, to further define our target customers and how to tell our story to them.
- Continue and update competitive analysis of the major alternatives to LearnTogether and develop approaches to address them.
- Create a strategy for marketing and client engagement
- Prepare a business plan and investor materials.
- Prepare a draft for a go-to-market name and brand strategy.
- Finalize revenue streams and projections
- Creating a company organizational structure for launch

3) Project: PolySTAT: Injectable Polymer to Stop Trauma Patients from Bleeding to Death

*Principal Investigator: Suzie Pun (Bioengineering) and Nathan White (Emergency Medicine)*

*CoMotion Technology Manager: Roi Eisenkot*

Blood loss accounts for 30-40% of trauma-associated deaths, and is in fact the leading cause of death in the initial hours after injury. Methods to restore haemostasis in external injuries include use of gel sealants and tourniquets, but there are few haemostatic agents that can be used systemically to stop internal, non-compressible and often fatal haemorrhage. Examples include blood components (e.g. plasma, fibrinogen concentrates) and recombinant proteins; however, blood components are costly and require specialized storage conditions, and also carry the risk of immunogenicity or infectious disease transmission. PolySTAT is a synthetic polymer that is uniquely positioned to fill the need for a simple, efficacious haemostatic agent without the above complications of biological materials.

In a recent animal trial (on rats) the researchers showed how injecting the synthetic PolySTAT resulted in 100% survival rates, compared with 20% of rats treated with a natural protein haemostatic agent, and 0-40% control arm survival rate.

The following is a link to a story featuring the technology on the UWToday portal: [bit.ly/uw-pun](bit.ly/uw-pun).

We are seeking an MBA student to:

- Conduct competitive landscape analysis, build the business case and identify the most relevant market segments.
- Perform cost analysis and compare to costs of existing biological offerings.
- Perform background research on regulatory issues that characterize therapeutics for trauma patients.
- Describe the development roadmap leading up to Investigational New Drug application.
- Spotlight on Developing Countries.
- Develop executive summary that may be used to attract potential investors.