

Hamilton Health Innovation Check-up: Meeting Minutes

May 2022

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STANDING AGENDA TOPICS:

- **Guest Speaker Discussion**: insights around the experience and expertise of an invited speaker, focusing on a subject that may be of interest to the broader community
- **Communicate**: share recent successes, upcoming events, innovation pipeline and new products, health innovation trends, etc.
- Collaborate & Accelerate: welcome new members to community, partnership opportunities, discover programming and resources available to the community, discuss market gaps and challenges, learn about potential funding opportunities, new RFPs issued, etc.

Facilitator & Note Taker Virtual Location

Alex Muggah, Director, Synapse Consortium

Join Zoom Meeting: https://zoom.us/j/405351918

Dial in: +1-647-558-0588,,405351918#

Register here:

https://us02web.zoom.us/meeting/register/uZQodOyppzoiQnRwfvVuEJ

tEMUpKPUZPzg

Next Monthly Check-up: June 27th 9:00 – 10:00am | McMaster Innovation Park (via Zoom) Please sign up to our <u>mailing list</u> to receive meeting minutes and other important updates.

Finding collaborative partners for health companies and researchers can be difficult. Synapse has created the <u>Hamilton Health Ecosystem Directory</u> and the <u>Health Innovation Partnership Portal</u> (HIPP) to facilitate finding new partners within Canada's leading health research and educational ecosystem located in in Hamilton, Ontario.

Minutes for our monthly check-up meetings are not published and are for reference purposes only. We do our best to ensure all information is accurately portrayed, and that no privileged/private information is inappropriately disclosed. Past meeting minutes can be access through a public Dropbox, using the following link.

For additional information on any subject, to contact a presenter directly, or should you have an adjustment to make to the notes made here, please contact: Alex.Muggah@SynapseConsortium.com. Updates will be reflected in a revised version of the monthly minutes.

As a result of the COVID-19, all in-person conferences and meetings have been cancelled. We are trying to track down events that will be held virtually and will try to keep our calendar up to date.

If you have an event that you would like listed here, please contact us at: info@synapseconsortium.com

Hamilton Health Innovation: Calendar Highlights

Check out Synapse's online calendar

<u>June</u>

- Jun 13-16: <u>BIO International Convention</u> (BIO)
- Jun 1-2: E-Health Conference and Tradeshow 2022 (Health Infoway, CIHI & Digital Health Canada)
- Jun 13-16: BIO International Convention (BIO International)
- Jun 13: <u>Connections @The Clinic</u> (McMaster'a The Clinic)
- Jun 14: <u>The Future of Health</u> (CityAge)
- Jun 20-23: Collision 2022 Conference (Collision)
- Jun 22: Lunch & Learn: How Will Al Impact My Small Business? (Innovation Factory)
- Jun 27: <u>Hamilton Health Check-up</u> (Synapse Consortium)
- Jun 29: 5th Annual Canada's Innovation Corridor Summit (Hamilton Chamber of Commerce)

July & Beyond

Jul 25: <u>Hamilton Health Check-up</u> (Synapse Consortium)

- Aug: <u>Startup Survivor Pitch Competition</u> (The Forge)
- Sep 19-22: Creating Communities of Innovation (AURP)
- Sept 22: Annual President's Golf Classic (Mohawk Foundation)
- Sept 28: LiONS LAIR (Innovation Factory)
- Nov 10-11: Clinical Trials Conference 2022 (Clinical Trials Ontario)
- Dec 10: I'm Every Woman: A Concert of Greatest Hits (Hamilton Health Sciences Foundation)

Looking to engage the Hamilton Health Ecosystem?



In partnership with Innovation Factory and Synapse Consortium partners, leverage up to \$100,000 to work directly with an academic or hospital partner in the Hamilton ecosystem. Funding will support collaborative projects for Ontario-based life science firms requiring

clinical/research expertise, evidence, or data to commercialize their innovation. Learn more about SOPHIE here



Leverage up to \$15,000 in funding to work directly with the Research Administration groups at Hamilton Health Sciences or The Research Institute at St. Joe's Hamilton to create the pre-trial protocols and documents required to undertake a commercialization project or

clinical trial in one of Canada's leading research hospitals. Learn more about HEALTHI here



Time allotted | 30 Minutes

Topic: Guest Speaker Discussion

Insights around the experience and expertise of an invited speaker, focusing on a subject that may be of interest to the broader community

Guest Speaker Discussion

Guest Speaker(s):

Joel Ironstone

Founder & CEO, <u>Ironstone Product Development</u> [presentation slides used, and are available upon request]

Discussion

[the following is a synopsis of the discussion, and has been lightly edited for length and clarity]

Introduction

Good morning, my name is Joel and I am the CEO of Ironstone Product Development (IPD), a regulatory medical device consultancy. Our firm fills quite a specific niche in the Canadian medical device ecosystem. Many consultants will do what companies tell them, and then execute based on their experience. Few regulatory consultants will tell you what to do. The team at Ironstone PD will direct our clients to critically evaluate what the right steps are, from concept all the way through to commercialization. We then fill those gaps, leveraging our experience to bring products to market a little more quickly than they would otherwise.

Today, I wanted to (a) go through a few case studies to give a sense of the types of things we've helped clients do; and (b) some key tips for companies – some key concepts that are often missing when clients come to us.

To date, we've helped close to 100 medical device companies in every aspect of their product development and regulatory pathway, with the exception that we don't manufacture products. We have helped companies source contract manufacturers and qualify them in order to help companies set up their manufacturing.

Differentiating Technology vs. Product

One of the things people often don't differentiate, particularly for medical devices, is the difference between a technology and a product. You can have a technology, but what product, what clinical need is that satisfying? How do you move technology to become a product?

We support engineering, electrical, mechanical, software development and we set up quality systems, based on ISO 13485 standards. We do a lot of clinical trial design, though we are not a CRO so we don't execute trials. However, we can help design your trial and negotiate with the FDA to ensure it's structured in the right way.

A major mistake is companies design trials that produce great publications, instead of trials that would enable a marketing clearance. There's a fundamental conceptual difference. Scientists want to generate additional questions – studies that answer a question but does not generate new questions, you're terminating this area of inquiry in your research. However, a medical device clinical study should produce a definitive answer, and not generate additional questions that could weaken your submission to FDA. We help clinician scientists modify their perspective, explaining to why a study published in a high impact journal may not translate to regulatory approval.



Ironstone PD Client Impact

The products we've worked on have generated over \$2 billion in revenue, representing everything from surgical robots to imaging devices for wounds to high frequency ultrasound to respiratory therapy devices, wellness products that aren't exactly medical devices and medical imaging software. Recently we've been doing a lot of Alrelated work, particularly around image processing for cancer diagnosis and neurological therapeutics and diagnostics.

To provide a sense of the type of work we do, I will share a few case studies of companies we've worked with and the type of support that we can provide. We've dealt with everything from the highest risk device to a wellness product, to something that sits on the outside of an incontinence device.

Case Study 1: Enabling Cancer Radiotherapy (indication identification)

One of our first engagements was helping to reposition a device that was intended to enable and potentiate cancer radiotherapy. Our client engaged us to figure out what was the right indication for their device. We supported product design and early-stage clinical studies to figure out what was required to get the product to market. The plan we developed helped them raise more than \$1.5 million. A complex product, it required strategic engagement with radiotherapy companies, to understand how the product would be regulated (i.e., as medical device or drug).

Case Study 2: Adult Incontinence Sensor (user interface & workflow)

We helped a company develop a device called SensaSure, which attaches to an adult incontinence product to detect when the product soiled. We did the engineering development and helped with clinical data. For this product, the challenge was around how to place a product into a nursing home in a way that doesn't interrupt day-to-day activities. How do you take this technology and make it easy to adopt and implement in that kind of environment – especially for support workers who may be new to the job. We spent a lot of time working on user interface and workflow, working out how to position this in a nursing home environment. Ultimately this product was acquired within two years by the world's largest absorbent goods manufacturers – a great win for the company. These guys were 19-21 when they exited, and this is this product's now in the market worldwide.

Case Study 3: Neurosurgical Ablation (product innovation)

Another company we supported was developing an RF neurosurgical ablation technology for pain management, and they wanted to figure out how to improve their physician productivity. With RF ablation, you're ablating one nerve at a time, one needle at a time. We developed a device that allowed the company to deliver RF ablation to multiple sites simultaneously. The goal was to improve throughput, doing ablation simultaneously, or positioning all needles together and pressing "go" to save time. We also helped developed a user interface, leveraging their existing device and screen. We also did the documentation for Health Canada, CE-mark, and FDA approval.

Case Study 4: Wound Imaging (study design)

This handheld device was a fluorescence wound imaging product. The company had some challenges with securing regulatory clearance before they engaged us. We supported them in obtaining denovo clearance from FDA followed by 510K. They performed one of the largest studies done in wound care, enabling very specific marketing claims. So, they're the only device now that can claim detection of elevated bacterial burden in a wound. Good study design allowed the company to squeeze out additional post-hoc analysis to secure clearance related to the ability to localize bacteria in the wound, which relates to the ability to effectively treat the wound. The lesson here is to design good clinical studies, which enables marketing and allows the company to maintain a



competitive advantage. Clinical studies really are, in terms of developing differentiation, one of the keys in medical device marketing.

Case Study 5: Patient Repositioning (compliance testing)

Another device, also used in nursing homes, was designed to help with patient repositioning when sitting in chairs. Basically, what happens is people tend to slouch when losing core strength or are suffering from dementia or cognitive impairment. In a nursing home, there are occupational health and safety regulations regarding what and how care providers can lift patients. At the time, personal support workers usually put a mat under the patient to help with repositioning. In addition, a single personal support worker isn't allowed to lift someone and reposition them in a chair, even if they wanted to. Some patients can be quite heavy.

The device the company developed rolls a mat into a chair (or wheelchair), allowing the care provider to automatically pull the patient up straight. It was a simple device; one of these things that once you conceive of it, it's going to work. It's just a matter of implementation. We did all the electrical and firmware and all the compliance testing. There were obviously safety concerns around pinch points and other aspects. Now this device is on the market in nursing homes across Canada and the US.

Case Study 6: Intercranial Stent (Regulatory Compliance)

This last product I wanted to show, as it helps to give a sense of the range of support we cover. The company had created an intercranial stent intended for aneurysms, a bifurcation. The current products can't be positioned in the bifurcation, it's hard to do that. Our client developed a novel non tubular stent. There were a number of challenges. We had to engage with FDA, European and Canadian regulators to address ribs sticking in the vessel (e.g., how do you ensure that they're safe? How do you implant this?). This is the highest risk device, as it is permanently implantable. We negotiated with Health Canada and the FDA, and were able to secure a class four Health Canada license, enabling the first in human study.

Considerations: FDA Breakthrough

There are a few things that we think about, when we initially engage a client, and I think medtech companies should consider them as well.

The US has a program called breakthrough designation for medical devices. Breakthrough designations have a significant impact, is novel and is addressing an unmet need. It enables additional, more intense feedback with FDA. For a start-up company, it provides differentiation for the FDA to say we are a breakthrough technology (can help to raise money). Immediately after securing breakthrough designation, clinical/preclinical data is required to show the product will work.

We've worked on several FDA breakthrough products, from spinal implants to improve recovery to a lower risk opportunistic x-ray device to identify people with low bone mineral density. The product doesn't have to be a high-tech, fancy implantable device, but it does have to address a real unmet need. The application is not challenging, a few pages of documentation and a brief argument. The cost and potential benefit, I think really makes sense.

It helps the company to formulate what the product is exactly doing (e.g., what is the clinical benefit that is delivered?). When engaging companies about the breakthrough, we find it generates some organizational growth, as they ask themselves: "if this is the clinical differentiation, how we would measure the impact". May have a technology that's great but may not exactly know where to place it. To get the breakthrough designation, the company has to determine the target patient population and therapeutic indication.



Considerations: Intended Use

I hoped to take a moment to discuss intended use, as this is the real difference between a technology and a product. The FDA depends on intended use for its product classification. Depending on what a technology is used for can change the amount of clinical data required, as well as the risk class. This can have a real impact on commercialization efforts – depending on the intended use for your product you can go from a six-month non-clinical effort to a multiyear multimillion dollar clinical project.

When thinking about a technology, you must ask: "what is it going to do?". For example, a novel AI system for dementia would require reflecting on whether it is a pre-screen for dementia or looking to evaluate the effects of interventions on someone who already has dementia. It can be the same technology, but the clinical question its addressing will drive everything else downstream. To articulate intended use, it is important to think about who's using the device, what the device is, where it gets used, when, why, and a little bit of how. The key thing is that it gets cleared when you get an approval with FDA.

Consideration: Make Sure your Product Works

There's a difference between whether a product or process can generate a publication if it actually works. When evaluating a technology it's not enough know how your own product works, but also understanding the other products that try to deliver a similar clinical utility. The goal is to be at least as good as those ones; or identifying a compensatory characteristic. Perhaps sensitivity isn't as high, but you can do it at home.

By way of example, a rapid antigen test versus a PCR test. PCR tests have better sensitivity and specificity, but they are less effective in some other ways because you need to process them in a lab. Rapid antigen tests fills a need, but what does it mean for a rapid antigen test to work? How would it be used? What is the minimum diagnostic accuracy that's necessary? How would you measure it?

People tend to avoid asking these questions because they have a technology and it can be uncomfortable to clearly articulate what it means for it to work. In part, because this implies they might determine that it doesn't work. With our clients we work through what is the fundamental assumption. For example: "This device detects cancer better than mammography." If that the fundamental assumption, then everything else is window dressing.

This needs to be done at the beginning of the commercialization process. Postponing an evaluation of the fundamental question of "does it work", will only consume more investor money. Important to try to answer that question early with clinical data. It doesn't matter how great the company team is, or we are as consultants, if the product doesn't work, we can't change the outcome. Figure this out first, and then deploy your resources accordingly.

Considerations: Workflow, EMC Compliance & (Early) Clinical Data

In addition to how the product works, it should also come with an understanding of the appropriate workflow required to integrate; otherwise, you'll find adoption a problem. For example, with the adult incontinence device we could identify when the briefs were wet, but that didn't automatically lead to workflow design that improves patient experiences. For care providers, if the device doesn't lead to change in workflow, it will just annoy them. They may still change briefs at the same prescribed intervals, but now they feel guilty because they're aware that the patients are wet during the interval.



Electromagnetic magnetic compatibility (EMC) compliance issues can be addressed early during a pre-screen. It's not hard to validate diagnostic devices clinically, particularly if they're not affecting user workflow. For non-invasive devices, companies can use an independent IRB to get a study going in weeks. If your device doesn't manage patient outcomes (i.e., measuring compared to something offline) Health Canada may not require an investigational testing authorization (ITA), you which will accelerate getting the data you require.

There is just a minor subset of things that you need to do prior to going to and securing early clinical data, particularly for a diagnostic device. Everything is a competition, especially for companies that are looking to raise money. To help with differentiation when raising money, it can be very useful to be the company that has early-stage clinical data showing that the product works. I really think you're ahead of the game in terms of being able to reassure investors that fundamental clinical risk is off the table.

Consideration: FDA Pre Submissions

Finally, I would like to talk about FDA pre-submissions (pre subs), which is a structured process for managing interactions with FDA about a future applications for approval. During my first engagement with client's I will encourage talking to the FDA to get feedback on what the company's regulatory classification is. This helps determine the type of clinical data that is needed. FDA will often say "we think you're too early for a pre-sub, but file a pre-sub". We encourage companies to file early, as it is similar in benefits to securing breakthrough.

Securing FDA pre-sub requires a company to formulate what the product is doing (e.g., what's the clinical workflow, how are we going to test it?). The benefit is that you get written feedback from the FDA. As well, companies speaking with investors can show their regulatory strategy, and say that they've spoken with the FDA and they are in agreement (and share minutes). You get an A+ for being able to do that.

The FDA will answer any reasonable questions you put to them, but they won't consult for you. A sober review of the product risks needs to be communicated to FDA. If the FDA's not aware of these risks, they won't be able to comment on them. How you ask the questions are important. You can't ask "what is my regulatory path" or "what clinical study should I do", but you can ask whether the FDA agrees with this proposed clinical study. The more information companies supply, the more accurate are the responses. We've seen many pre-subs that didn't have enough information, and thus didn't ask the right questions.

Questions & Answers

Question: With regards to marketing and getting to market, is that something that Ironstone PD supports companies with? Or do you have partners that you work with?

A: We do some early-stage market strategy in terms of indication and how that would line up. But we typically end at transfer to production. We are really product and clearance focused. Most of what we're dealing with are novel technologies that don't have an existing market.

It's a very specific talent to say: "how do we actually create a market for a product that doesn't exactly exist?" and most who've done that are in the US. There are not many in Canada who have built a business taking a novel product and made a market out of it. As a result, for those looking for these kinds of services, we often work with people in the US. That said, there are a few people in this meeting who've done this. Going through distributors is often a challenge because they will sell what's easy to sell through their existing channels.



Question: We are about to start a clinical trial at MacMaster to assess safety, and the electric components of our SaaS device. Do you provide that kind of services, or do you have any connection to pass it in terms of its 60601? We have a waiver from health Canada, so it's not a class two class one and there is no direct contact with patient, but we need to do a visibility study.

Answer: If it's just software and looking at images obtained through the standard course of a colonoscopy, then you wouldn't have electrical safety requirements. If the product is an electrical device and needs service, we don't execute compliance testing (we work with MegaLab or QD), but we determine what testing is necessary and make sure that the right documentation is secured to get certification. I suspect that if your device is SaaS, and you've got a waiver from Health Canada saying it's not a medical device in the context of the study, then you are probably okay.

I think your real validation requirements would be on some sponsor risk to make sure that you don't do a study with software that doesn't work and get a result that you can't reproduce or doesn't reflect device performance. I don't think there would be safety requirements, but I'd need to better understand what the device is and what it does before providing a definitive answer.

Question: What, if anything, do you need from the community going forward? What resources, capabilities or access to infrastructure would allow you to be more successful and more capable of supporting medical device companies that you are consulting to?

A: A lot of our clients need clinical data. So ,connections with hospitals are really helpful for us in terms of principal investigators (PIs) that could execute clinical studies. PIs not associated with teaching hospital can also be useful, because it tends to be a little easier to do studies there.

We're always looking for good talent as well. One place that we would be interested in engaging a little earlier is with investors, helping them evaluate opportunities. We've done some due diligence work, as they onboard companies to make sure their investment is used efficiently. That's one of our next steps, really to work with investors and help make sure that the plan that their funding is rational.



Time allotted | 15 Minutes

Topic: Communicate

Recent successes, upcoming events, innovation pipeline, new products, health innovation trends, etc.

Discussion	Presenter
OmniaBio announces \$90M from private investor: CCRM's capabilities go from clinical to commercial scale	Stacey Johnson (CCRM)
OmniaBio, a subsidiary of CCRM, has executed a strategic agreement with Medipost, a global leader in stem cell therapeutics. Medipost is acquiring an interest in OmniaBio from CCRM for cash of \$30 million and is investing an additional \$60 million into OmniaBio. OmniaBio will start construction at McMaster Innovation Park this summer, an overall project worth \$580 million.	(com,
OmniaBio is expected to be Canada's largest contract development and manufacturing organization (CDMO) for the manufacture of cell and gene therapies. OmniaBio will provide pivotal/Phase III and commercial-scale manufacturing of gene-modified cells and viral vectors that is an expansion of the clinical-stage capabilities already offered by CCRM, a leader in developing and commercializing regenerative medicine-based technologies, and cell and gene therapies.	
Building on CCRM's existing expertise, OmniaBio will work with a variety of cell types, such as T cells and induced pluripotent stem cells. OmniaBio's manufacturing platforms are customized for viral vectors, as well as autologous and allogeneic cells.	
There is a manufacturing capacity issue in the cell and gene therapy industry due to the large volume of products in clinical trials, with demand outstripping CDMO availability by at least five times. In the first phase of construction, OmniaBio will build an approximately 85,000 ft ² (7,897 m ²) facility, equipped with 15 clean rooms and staffed by 500 employees, which is expected to be completed in 2024. With further planned expansion, OmniaBio and CCRM combined will have more than 50 clean rooms and over 1000 employees when you include CCRM's Centre for Cell and Vector Production at the MaRS Discovery District in Toronto, a partnership with UHN.	
To read the full article, click <u>here</u>	
As part of its ongoing commitment to support economic recovery, promote product commercialization, and facilitate job growth, Innovation Factory is pleased to announce it is accepting applications for the second cohort of the Hamilton Ecosystem to Accelerate and Leverage Trials of Health Innovation (HEALTHI) program. Innovation Factory is receiving up to \$300,000 in funding from the National Research Council of Canada Industrial Research Assistance Program (NRC IRAP) in support of the program, which will enable life science companies to collaborate with world-class research hospitals. Ultimately, this will lead to increased product development and innovations within the healthcare sector.	Jennifer Gauvreau (Innovation Factory)
The HEALTHI program is accessible through an application process administered by Innovation Factory, in collaboration with the Synapse Life Science Consortium (Synapse). Successful applicants will have the opportunity to engage with key stakeholders as part of a future commercialization project or clinical trial with research groups at either Hamilton Health Sciences or St. Joseph's Healthcare Hamilton.	



Discussion	Presenter
Read the full press release here	
ToeFX reaches milestone of 100 clinics across Canada	Monika
ToeFX, a healthtech startup offering a safe, effective treatment for nail fungus (onychomycosis), celebrated reaching a new milestone with their innovative ClearToe Therapy Light, which is now available at over 100 clinics from BC to Newfoundland. ToeFX is a longstanding Forge client and developed a non-invasive, non-toxic, and painless treatment for clinicians to clear up nail fungus within eight to ten treatments using their innovative ClearToe Therapy Light.	Yazdania (ToeFx)
The treatment is authorized by Health Canada and uses photodisinfection technology together with ClearToe Serum, without the use of lasers. Prior to ToeFX, Canadian foot care clinicians had only a handful of options at their disposal – oral or topical prescription medications, laser therapy or nail removal.	
ToeFX has seen consistently high demand for their ClearToe Therapy light, with 30 clinics adopting the therapy method across Canada within the first quarter of its launch to the market. Clinicians value the ease of use and affordability of the therapy method, while patients enjoy having non-invasive treatment option that does not cause any adverse effects. The Hamilton-based startup is deeply committed to researching, testing. and manufacturing their products in Canada and is currently developing novel diagnostic techniques.	
HHS patients to move from one MyChart to another	Alex Muggah
Hamilton Health Sciences (HHS) patients currently using the regional MyChart app to access personal health information, like hospital test results, are about to get a new and improved online tool. The new MyChart app by Epic will be available to all HHS patients – including those already using the existing version – beginning June 4. The new MyChart app, managed by HHS, replaces the regional tool currently available to HHS patients through Sunnybrook Hospital.	(Synapse)
Read the full CanHealth Technology article here St. Joe's, Hamilton conducts robotic esophagectomy	Alex Muggah
With a new, fully robotic approach, thoracic surgeons at St. Joseph's Healthcare Hamilton have changed the way that esophageal cancer surgeries are performed. It's the most significant advancement in surgery for esophageal cancer in Canada in more than two decades.	(Synapse)
"While esophageal cancer rarely makes headlines, it has the second highest mortality rate of all cancers," said Dr. Waël Hanna, a thoracic surgeon at St. Joe's and the head of research within the hospital's Boris Family Centre for Robotic Surgery. "It's so deadly because the esophagus is deep in the throat and thorax and has historically been difficult to operate on using traditional surgical methods."	
The complication rate for those undergoing a traditional esophagectomy (a procedure to remove the cancerous portion of the esophagus while pulling the stomach up in the chest cavity to reattach it) is as high as 60 percent.	
Read the full Canadian Healthcare Technology article <u>here</u>	
Nowhere to grow: Canada's biotech sector is booming, but a lack of lab space has some companies looking south (The Logic, subscription required)	Alex Muggah (Synapse)



Discussion	Presenter
Laboratories—whether wet, where chemicals, drugs and biological matter can be tested and analyzed; or dry, with a focus on computers, electronics and other such instruments—can't operate just anywhere. According to Daniel Lacey, practice lead for life sciences at real estate services firm CBRE in Toronto, they need specialized infrastructure. "The costs are huge," he said. "They're more than any other real estate asset."	
The tight market is especially challenging for scaling companies that have raised some money but aren't associated with research hospitals or universities, said Alex Muggah, director of Synapse, a life-science industry coalition focused on supporting the sector in and around Hamilton, Ont. "Once you have achieved a certain size and scale of capital raise, your company is able to build out its own facility," he said. "But most life-science companies in Canada are startups." Muggah said venture capital investors don't have the appetite to wait 18 to 24 months for a company they've just funded to build a lab space. "They want to be hitting performance milestones in 18 months, not to start working."	
In the meantime, companies in the GTA have few options. The McMaster Innovation Park in Hamilton has begun a "mega hub" expansion that will host 1.3 million square feet of new labs. "McMaster Innovation Park is the only real game in town right now," said Lacey. "There are projects planned in Toronto, but there's nothing under construction."	
Read the <u>full article</u> at The Logic (subscription required)	
McMaster entrepreneur (Synmedix) uses baking soda to supercharge antibiotic Helped by \$300,000 from the <u>seed fund</u> sponsored by McMaster's vice-president, research, Eric Brown's start-up firm Synmedix will soon test a new topical preparation of bicarbonate mixed with the antibiotic azithromycin to treat infected diabetic foot ulcers (DFUs).	Alex Muggah (Synapse)
This potentially game-changing solution is called BCX and, if successful, could both combat drug-resistant bacteria and help develop a thriving biotech sector in Hamilton.	
"It is crazy because it is so simple," said Brown, a Distinguished University Professor of biochemistry and biomedical sciences at McMaster and a member of Canada's Global Nexus for Pandemics and Biological Threats as well as the Michael G. DeGroote Institute for Infectious Disease Research.	
Brown said there are currently no topical antibiotics that can treat diabetic foot ulcers, which every year affect 140 million people with diabetes worldwide. Of these patients, half will suffer a diabetic foot ulcer infection, which is often difficult to treat with oral antibiotics, owing, in part, to drug-resistant bacteria.	
Read the full Brighter World article <u>here</u>	
The three things Ontario needs to do to make its health-care system sustainable in the long term (Opinion, Hamilton Spectator)	Alex Muggah (Synapse)
With an election fast approaching, the future of health care is top of mind for many people in Hamilton. The COVID-19 pandemic has placed incredible strain on the health-care system we all rely on. As a result, no matter which party is elected in June, the Government of Ontario must continue with significant, long-term investments in health services and planning. Three areas of	



Discussion	Presenter
improvement in particular deserve attention if we are to ensure timely access to health services for everyone who needs them.	
Reducing the service backlog that has accrued during the pandemic is a top priority. Postponed diagnostics, surgeries and other delayed procedures have increased the amount of untreated illness in our communities. There is now an estimated backlog of 25,000 adult and pediatric patients waiting to be seen in Hamilton and the surrounding region. This cannot be overcome without aggressive investment in innovative solutions to increase health service capacity. We cannot go back to the way things were before the pandemic — we need to find new approaches.	
It is also vital to renew the oldest hospital facilities in Ontario. This was made evident during the pandemic, as COVID-19 spread quickly through hospital wards built to meet infection standards from a bygone era. Ambulances lined up outside facilities without adequate beds. Fortunately, in Hamilton, the redevelopment of Juravinski Hospital was recently approved by the province to proceed to the next stage of planning. This project will see the replacement of several outdated patient care towers. It will add over a hundred new hospital beds. To see this through, our community must rally behind the project, advocate to the province for its quick completion and fundraise in support of the costs not covered.	
Still, new facilities are only as good as the staff inside them. Health human resources in Ontario, and much of Canada, are at a critically low level. Employment vacancies are rising for the workers we need to maintain timely access to care. This includes registered nurses, health care aids and certain types of physicians. Training, recruiting and retaining sufficient health-care workers to meet the needs of a growing and aging population will make or break the future of our health care system. Hamilton Health Sciences has been working with local academic partners, particularly Mohawk College, to bring nursing trainees into the workplace as quickly as possible. Investing to expand this program would help alleviate our shortages in the near term.	
Our health-care system is experiencing a pivotal moment of change and opportunity. The ideas above are only a few of the many we must consider.	
Read the full article <u>here</u>	
Able Innovations announces \$7.5 million to take the pain out of patient transfer (Betakit)	Alex Muggah (Synapse)
The Toronto-based robotic medical device startup (and Innovation Factory HEALTHI program participant) focuses on the problem of patient transfer—a run-of-the-mill, labour-intensive procedure that usually involves some combination of porters, nurses, and orderlies lifting a patient from point a to point b, sometimes using bed sheets or a slider board.	(S)apse)
The typical patient transfer process as "pretty crude," adding that it can cause pain to patients and result in hospital staff experiencing injuries. Amid an already short-staffed healthcare system during COVID-19, the issues associated with this routine task have become magnified.	
Enter Able Innovations, which has built a robotic medical device designed to address the problem of patient transfer, called the ALTA Platform. To date, the startup has secured \$7.5 million CAD in previously unannounced venture capital and grant funding, and the support of doctors like Puri to develop and begin rolling out its solution.	



Discussion	Presenter
"The best solutions are the ones that change the standard of care, and sometimes they're super, super simple," said Puri. "And this is that thing. It's very, very simple—it's a lateral transfer. It happens millions, if not billions of times a day, around the world, but nobody cares about it."	
Read the full Betakit article <u>here</u>	
City of Hamilton investing \$3.6 million in air purification system improvements across City facilities	Alex Muggah (Synapse)
With \$3.6 million in funding support through the federal government's Investing in Canada Infrastructure Program (COVID-19 Resilience stream), the City of Hamilton is making air purification improvements across City facilities over the coming months with the goal of improving air quality and reducing airborne and surface contaminants such as bacteria, pollutants and viruses.	
A tender for the remaining improvements at City facilities as part of this federal investment is expected to be released later this year, with improvements being completed by December 2023.	



Time allotted | 15 Minutes

Topic: Collaborate & Accelerate

Partnership opportunities, programming and resources available to the community, market gaps and challenges, learn about potential funding opportunities, discuss new RFPs issued, etc.

Discussion	Presenter
Want to Connect with your Ecosystem: Check out the Synapse Health Ecosystem Directory	Alex Muggah (Synapse)
Synapse has created a Director of +200 private- and public-sector organizations in the Hamilton (and regional) health innovation ecosystem which work alongside the Synapse Consortium to support of the commercialization of health innovation. Learn more about what others are up to, and identify potential collaborative partners at: www.synapseconsortium.com/directory	
Engaging Mohawk College's IDEAWORKS	Andrea Johnson
IDEAWORKS projects in general (of which, MEDIC is one area) which was provided and may help with identifying if Mohawk College can support our companies with projects. This might be a refresher for some or all of us, but highlighting nonetheless: Tips for Innovation Factory Referrals to IDEAWORKS • Our four innovation centres (MEDIC for Digital Health, AMIC for 3D printing, EPIC for energy efficiency related projects and MTIC for Medical Technologies related challenges) are active during this time- but note that due to existing commitments, are often looking at projects one month to three months in the future. • Other areas of expertise are on a case by case basis, especially this year, with a number of our faculty committed to teaching and revamping courses • The ideal applied research partner is one that is in the scaling stage; they have some revenue and can meet a lot of the funding agencies criteria for funding or want to self-fund a research project. Typically what we look for is 2+2; two years in business with two employees • We recommend working with us on projects that aren't mission critical but can help the company explore an innovative idea. What about start-ups? • If they require a few tips or advice, we can normally chat with them (or if there is a critical mass -like five or six companies in a space-, we can do a webinar type discussion). • They can see about the availability of capstone projects, where students generally work on projects for a four month period, for free, in order to get course credit. It may help with MVPs. Contact Andrea Johnson for more information: andrea.johnson4@mohawkcollege.ca	(Mohawk College)
The CONNECTION - McMaster University Online Partnerships Portal!	Gay Yuyitung
The Connection is a new program offered by McMaster's Office of Community Engagement (OCE) designed to facilitate online, mutually beneficial partnerships between campus and local Hamilton community organizations. As communities look for ways to adapt and rebuild in response to COVID-19 The Connection will make the process of addressing Hamilton community and University identified needs easier by providing online tools and resources. It's a way for everyone who sees themselves as part of a collective community-campus effort to connect and respond to COVID-19 locally	(MILO)



Discussion	Presenter
Collaborating with McMaster Institute for Infectious Disease Research (New Intake Form)	Gay Yuyitung (MILO)
In addition to our ongoing COVID-19 research initiatives at McMaster, the Michael G. DeGroote Institute for Infectious Disease Research is mobilizing its strong research	
community to assist Canadian researchers and businesses in their attempts to find solutions to the international crisis. The IIDR teams have the capacity to assist with the testing of anti-viral compounds and products, as well as the testing of products or devices aimed at	
sterilization. This includes new methods for sterilizing personal protective equipment. They are able to offer services in the following areas:	
 BSL2 cell culture infection with representative human coronaviruses; Testing of methods or products that are designed to inactivate the virus; Biochemical/enzyme studies with anti-viral agents. 	
Cell culture and small animal models of SARS-CoV-2 infection can be performed in McMaster's secure biosafety level 3 facility. Availability for BSL3 testing is very limited, and projects requiring this type of work will be screened and prioritized by an internal committee.	
If you have a product or innovation that you are interested in pursuing further and feel that we could be of assistance to you, please <u>reach out to us through the online form</u> . Each	
project will be evaluated to determine if McMaster has the capabilities and capacity to perform the required testing.	
Hamilton-based technologies available for licensing	Glen Crossley (MILO)
Each year researchers at McMaster, <u>Hamilton Health Sciences</u> , and <u>St. Joseph's Healthcare Hamilton</u> make new discoveries that lead to new products, services, or process improvements to help companies expand their pipeline or increase their productivity. The business development team at <u>MILO</u> is here to help you tap into and access these discoveries as efficiently as possible. MILO's objective is to support effective transfer of these technologies to companies for social and economic benefit and enable the continued growth of research excellence at the institutions.	
Please contact <u>Glen Crossley</u> , <u>Associate Director</u> , <u>Business Development and IP</u> or search the list to see some of the technologies currently available for licensing or further R&D	
Hamilton Innovation Partnership Portal	Michael Jones (Synapse)
Synapse has created the <u>Hamilton Innovation Partnership Portal (HIPP)</u> to make the process simpler and more streamlined to find new partners within Canada's leading health research and educational ecosystem. It is a way for companies to interact with the Hamilton community. A streamlined approach, to have Synapse represent everyone. We've set up an intake form for companies to direct request to the portal. Portal is online through the Synapse website: http://synapseconsortium.com/partner/	
Submit Community Events on the Innovation Factory Calendar Our calendar is home to Innovation Factory workshops and networking events as well as events from the community which help support our local entrepreneurs and businesses. If you have an event which may a fit, please submit it and we will review it within five business days.	Annie Horton (Innovation Factory)



	Discussion	Presenter
Govern	ment Call for Innovative Solutions	Innovation Factory &
•	<u>Call for Suppliers</u> (Federal): In support of the Government of Canada's <u>whole-of-government response to Coronavirus disease (COVID-19)</u> , they are asking suppliers about their ability to provide a variety of products and services.	Synapse Consortium
•	<u>Call for Suppliers</u> (Ontario): request for information from companies able to supply emergency products to help fight Coronavirus	
•	Federal Government <u>Call to Action for Canadian Manufacturers</u> to support businesses to rapidly scale up production or re-tool their manufacturing lines to develop products made in Canada that will help in the fight against COVID-19. Please refer to the <u>product specifications and requirements</u> for Canada's medical supply needs.	
•	Health Canada will facilitate earlier access to a vaccine, or therapeutic product for COVID-19 to expedite the review of COVID-19 related health product submissions and applications.	
•	Government of Canada is speeding up the importation and sale of medical devices used to diagnose, treat or prevent COVID-19. Here is information about expediting access and authorization for diagnostic devices for use against coronavirus (COVID-19).	
•	Government of Canada will launch specific challenges through the <u>Innovative Solutions Canada (ISC)</u> program and will rapidly select the best projects to accelerate development and testing of promising innovations that can have a direct impact on our health care response. Also use the ISC Testing Stream to become the first customer of these innovative products.	
•	The <u>National Research Council of Canada (NRC)</u> will organize an NRC COVID-19 Challenge Program, composed of teams of government, academic and private sector partners to address a range of medium term PHAC and HC needs, including personal protective equipment, sanitization, diagnostic and testing, therapeutics, and disease tracking technology. The most promising solutions will be selected for	
•	procurement, working with Innovative Solutions Canada. <u>DISRUPT COVID-19</u> , a Government of Canada virtual forum that will include representatives from the National Research Council (NRC), the Industrial Research Assistance Program (NRC IRAP), Health Canada, the Public Health Agency of Canada (PHAC) and Innovation and Science, Economic Development (ISED), is being organised as a pilot initiative with the goal of getting technologies on the ground helping patients and health care professionals as fast as possible.	
•	Next Generation Manufacturing (NGen) will invest \$50 million in Supercluster funding to support companies as they rapidly respond to the COVID-19 pandemic by building a Canadian supply of essential equipment, products, and therapeutics. For more information on NGen's COVID-19 Response Program, see the <u>full bulletin</u> , review the <u>project guide</u> , and share your capabilities in the form below. Ontario Website for PPE Suppliers to Post Products for Sale: Review a list of companies that sell personal protective equipment (PPE) and other supplies to keep your employees and customers safe from COVID-19. Apply to be added to the workplace PPE supplier directory	
unlockii	ital Technology Supercluster has launched the COVID-19 Program is focused on ng solutions to protect the health and safety of all Canadians and our economy on the development, deployment, and scaling of digital technologies.	



Our Synapse Consortium partners are at the forefront of addressing COVID-19 in the City of Hamilton, and across Ontario: doctors and nurses caring for patients, public health officials coordinating city-wide responses, conducting epidemiological research at Canada's leading research hospitals, and innovative companies developing products to provide needed supplies and services.

Throughout all of this, Synapse remains committed to our core goal of facilitating connections across the Hamilton health ecosystem, bringing public- and private-sector actors together to enable innovation and resolve pressing health challenges. While Synapse staff are not in the office, we're still providing support virtually – so please continue to reach out and find out how we can help!

If you want to get in touch, please contact <u>Alex Muggah</u>, Director of the Synapse Consortium. Separately, we've assembled links to information that has been compiled by organizations across Ontario (and Canada) to assist you with navigating the COVID-19 pandemic.

Learn More About COVID-19: Online Resources

Synapse Consortium partners have put together a significant amount of information and updates on the status and activities related to containing and addressing COVID-19 for both businesses and citizens in the region:

Hospitals and Research Centres

- Hamilton Health Sciences: <u>COVID-19 Updates</u>
- St. Joseph's Healthcare: Research Institute and Hospital Update
- McMaster Institute for Infectious Disease Research: News and Updates
- McMaster University: <u>COVID-19 Update</u>
 Mohawk College: <u>COVID-19 Update</u>

Hamilton Community Partners

- Mohawk College Collaboration Landing Page
- McMaster University Collaboration Landing Page
- City of Hamilton: City Response and Resources
- Hamilton Public Health: Learn more about COVID-19
- Innovation Factory: COVID-19 Info Centre
- Hamilton Chamber of Commerce: Resources for businesses
- Hamilton Spectator: What you Need to Know in Hamilton
- Buy-Local (Hamilton): Hometown Hub

Government and Agencies

- Health Canada: COVID-19 Information and Resources
- OCE: <u>Collaboration Platform</u>
- Government of Ontario: COVID-19 Information for Ontarians
- Government of Canada: <u>Business Support</u>

For Companies Making COVID-19 Related Medical Products

- Call for Suppliers (Ontario)
- Call for Suppliers (Canada)
- Health Canada: Expedited Review of Health Product Submissions and Applications for COVID-19
- Health Canada: Applications for medical devices under the Interim Order for COVID-19 use
- Health Canada: Expedited Access and Authorization to make COVID-19 personal protective equipment
- Health Canada: <u>Diagnostic devices for use against coronavirus (COVID-19)</u>

