BRIGHTSQUID

Health City

Digital Health Integration Readiness Program (Pre-HaTCH)

Call for Expressions of Interest

Deadline for submission: Feb 15, 2021

Program inquiries:
admin@edmontonhealthcity.ca

Website: https://bit.ly/398ObSO

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Organizational Profile

Health City is a Canadian not-for-profit Corporation that works with clinicians, innovators, philanthropic organizations, and companies to develop new pathways of care that can drive better health outcomes and economic development in the health sector.

More detailed information on Health City is available at www.edmontonhealthcity.ca

Brightsquid Secure Communications Corp. is a Calgary-based health tech company with over a decade of success delivering healthcare software applications throughout North America and Europe. Brightsquid's applications are built on a privacy-compliant engine that maintains patient information safety to the letter of the law in the US, Canada, and EU. The Brightsquid Executive, Board, and Advisory are comprised of experts in privacy compliance law as it relates to technology in healthcare. The company has helped establish ongoing privacy compliance at hundreds of healthcare organizations (including technology vendors) and has delivered accredited privacy training to thousands of healthcare professionals.

More detailed information on Brightsquid is available at www.brightsquid.com

Introduction & Project Description

Alberta currently has a growing number of digital health companies that face similar challenges when attempting to commercialize their product or service. In many cases, these challenges are similar in other industries, however the one significant barrier to entry which is unique to health is the lack of integration capabilities with clinical information systems (e.g., Electronic Medical Records [EMRs]). This lack of integration makes it even more difficult for small and medium enterprises (SMEs) in the health space to gain early traction with customers as these new digital health technologies do not seamlessly integrate into existing clinical workflows. In many cases, clinicians may be interested in acquiring the new technology but the burden of working in multiple systems is enough of a deterrent to stop the purchase. The hurdles and costs associated with clinical integration and ensuring privacy and security compliance are high and act an additional barrier. These barriers may even prevent SMEs from entering the space as the commercialization pathway to reach full integration and interoperability is not worth the investment, even if the technology has the ability to offer significant value to the healthcare system.

Recognizing these barriers, Brightsquid developed the Health Technology Commercialization Program (HaTCH). HaTCH members (Hatchlings) gain access to that foundation of compliance, as well as expert training, integrations with leading medical software, and an existing market of hundreds of thousands of end users. Completion of the program enables SMEs to be integrated into the TELUS Health Exchange to connect directly into TELUS Health EMRs, solving one of the largest hurdles facing digital health companies. Moreover, Brightsquid's platform also provides an opportunity for successful SMEs to scale and expand to other jurisdictions.

After offering an initial cohort of HaTCH, Brightsquid identified the various stages of readiness of the Hatchlings. While the focus of the program is aimed at technical readiness (i.e., privacy, security, regulatory, etc.), it was difficult for SMEs to advance in this area with differing levels of business and clinical readiness, which are equally important to the success of a company.

The Digital Health Integration Readiness Program is a joint initiative between Health City and Brightsquid with funding support provided by Western Economic Diversification. The program has been developed to provide SMEs with the training and education required to address challenges related to privacy, security, regulatory, and integration activities. This program aims to address existing gaps and provide SMEs with the fundamental understanding of technical readiness, ultimately preparing them for the ability to tackle the complex integration requirements that are critical to success. SMEs that complete the program can expect the following:

1. Help early-stage companies understand the health information regulatory requirements for their product to commercialize
2. Provide basic knowledge for software development practices to incorporate privacy and security principles to be successful in the health sector
3. Provide a clear overview of Canada's healthcare delivery and health tech ecosystems
4. Provide resource options at the conclusion of the course to clarify the road to market and commercialization
5. Provide a 1:1 review session to assess business readiness and be provided with resources and direction to address identified gaps.

The long-term goal of this program is to better prepare SMEs for progression through the health commercialization life cycle and provide a feeder into the full HaTCH program, ultimately providing high quality digital health products and services to the Alberta and Canadian market.

Project Timelines

The program will recruit up to twenty (20) Alberta-based companies/participants, to partake in the initial cohort beginning in March 2021. Those selected will be required to complete a four (4) week, interactive program.

Session	Details	Date & Time
Session 1	**Healthcare Information Governance – what is it and what are my obligations?**	Thursday March 4, 9AM – 12PM
Session 2	**Healthcare Information Governance – what are the risks and how do I manage them?**	Thursday March 11, 9AM – 12PM
Session 3	**Healthcare Innovation – impacting the lives of patients and providers**	Thursday March 18, 9AM – 12PM

Session 4	**Health Ecosystem & Partner Opportunities**	Thursday March 25, 9AM – 12PM
Business Readiness Session	1:1 review of business readiness assessment and guidance on resources and next steps	To be scheduled during the first week of the program

Selection Criteria

All Expressions of Interest from Alberta SMEs will be evaluated based on the following:

1. Early stage, start-up or SMEs that are residents of Alberta. An experienced management team and financial resources to commercialize their product will be considered an asset.
2. Technology that has high potential or is ready for commercialization and usage by health care professionals and patients. Technologies with initial market traction will be considered an asset.
3. Technology with high potential for improved clinical and economic outcomes.
4. Early stage, start-up or SMEs that are in active or have had recent discussions with one or more health system payers regarding procurement will be considered an asset.

Note: Early stage and start-up companies with developing digital health solutions or companies pivoting into health technologies will also be considered for admission to the Program.

SME Financial Contributions

Selected participants will receive complimentary admission to this program. It is estimated that the cost of the program is ~$5,000 and registration fees are being covered as part of the WD initial investment to establish program curriculum. Successful applicants are eligible to have up to 3 individuals attend the program sessions.

Expression of Interest

Interested Alberta-based SMEs are encouraged to submit an Expression of Interest (EoI) to Health City by no later than February 15, 2021 for consideration for the cohort that will begin on March 4, 2021. The EoI should be a maximum of 5 pages (excluding appendices) outlining the following:

1. Company overview and history, including identification of key members of the management team, and team members (part- and full-time).
2. Proposed value proposition for the technology compared to current standard of care or unmet clinical need. The target population expected to benefit from the technology, as well as the clinical care pathway, and key stakeholders should be identified.
3. Technology technical overview, trials/usage of the technology to-date (if any), and current state of evidence for the technology's safety, efficacy and effectiveness (if any).

4. A summary of financial strategy/strength to commercialize a product (e.g., available internal resources, funding, investment or loan upon receipt of purchase order, etc.).
5. Completion of the Health Innovation Client Journey Map[1] (Appendix A).
6. Confirmation of availability to attend all sessions and names of up to 3 participants.

Successful applicants will be contacted by Feb 22, 2021.

EoIs or any questions or comments can be sent to admin@edmontonhealthcity.ca.

[1] "Health Innovation Cycle." Alberta Innovates. Accessed January 26, 2021. [Word file]. Retrieved from: https://albertainnovates.smartsimple.ca/files/646815/f125423/AI_Health_Innovation_-_Intake_Checklist.docx

Appendix A - Health Innovation Client Journey Map

Client Journey	Product-Market Fit	Business Readiness	Regulatory Compliance	Product Development
Discovering	☐ Unmet clinical need identified and validated through secondary research.			☐ State of the art summarized
Ideating	☐ Target clinical population identified and characterized. ☐ Current clinical care pathway and workflow described. ☐ Feedback from ≥5 clinicians or consumers.	☐ Target market identified and characterized. ☐ Key stakeholders identified. ☐ Envisioned benefit statements for patients, payers, and providers.	☐ Familiarization with local regulatory requirements and processes.	☐ Idea screening & selection completed. ☐ Hypothesis and experimental design completed.
Conceptualizing	☐ Technology-adjusted care pathway and workflow described. ☐ Quantifiable health outcome targets developed. ☐ Feedback from clinicians or consumers in ≥ 5 different settings.	☐ Competitive analysis and competitive positioning completed. ☐ Path to payment plan or reimbursement described. ☐ Stakeholder management plan developed. ☐ Proposed Business Model. ☐ Foundational business agreements drafted (i.e., initial ownership and rights).	☐ Comparable / predicates identified as necessary. ☐ Preliminary intended / indications for use drafted. ☐ Regulatory categorization and class determination ☐ Hazard and risk analysis.	☐ Key Proof-of-Concept features documented. ☐ Proof-of-concept and mechanistic action experiments completed. ☐ Intellectual property strategy drafted and IP disclosure filed as needed. ☐ Functional requirements document drafted (i.e., system, module, interface, performance specifications).
Committing	☐ Technology-adjusted care pathway and workflow updated. Use-case scenario developed. ☐ Clinical Advisory team formed. ☐ Feedback from clinicians or consumers in ≥10 settings.	☐ Feedback from ≥5 economic buyers. ☐ Revised Business Model. ☐ Business Mentorship Circle formed. ☐ Foundational business agreements executed (i.e., initial ownership and rights).	☐ "Essential Requirements" checklist drafted and pre-submission meeting complete. ☐ Instructions for Use drafted. ☐ Cyber security plan drafted.	☐ "Looks Like" prototype drafted. ☐ "Works-Like" experiments initiated. ☐ Software architecture, usability assessment, and interoperability plan developed for digital components. ☐ Provisional IP filed & Freedom-to-Operate assessment completed.
Validating	☐ Feedback from clinicians or consumers in ≥20 settings. ☐ Feedback from ≥3 Key Opinion Leaders. ☐ Peer reviewed experimental results published.	☐ Investor-ready business plan completed, including costing for manufacturing. ☐ Path to payment plan or reimbursement revised. ☐ Advisory Board development plan completed. ☐ Key team members committed. ☐ Pre-seed investment secured. ☐ Feedback from ≥10 economic buyers received.	☐ Necessary regulatory approvals granted to move into clinical trials. ☐ Institutional Review Board (IRB) documents for clinical investigations drafted. ☐ Draft product claims ☐ Cyber security plan drafted (i.e., HIPAA, GDPR). ☐ Preliminary manufacturing plan (GMP).	☐ "Works-like" pre-clinical experiments completed, and performance specifications documented. ☐ "Looks-like" prototype available and product requirement document drafted (design freeze). ☐ Full IP protection strategy enabled (IP applications as necessary). ☐ Software architecture, usability assessment and interoperability plan validated.
	☐ Safety/efficacy validation trial(s) conducted, and endpoints achieved. ☐ Demo feedback from ≥25 users.	☐ Advisory Board in place. ☐ Feedback from ≥20 economic buyers and purchasing expression of interests from >1 buyer. ☐ Further funding secured (2nd pre- or Series A).	☐ IRBs documents for clinical investigations submitted and approved at ≥1 institution. ☐ Data requirements for regulatory approval reviewed and confirmed. ☐ GMP-compliance achieved, and pilot lot produced. ☐ Cyber security certifications obtained.	☐ "Works-like" clinical experiments completed, and performance and safety specifications updated. ☐ "Feels-like" usability data collected.
	☐ Efficacy trials conducted. ☐ Peer reviewed data from safety/efficacy trials published.	☐ Purchasing intent from ≥10 buyers obtained. ☐ 2nd round of institutional investment secured. ☐ Reimbursement path finalized.	☐ Submission package ("Technical File") completed and submitted. ☐ Quality System Plan for (c)GMP-manufacturing process drafted finalized.	☐ "Works-like" clinical experiments completed, and performance and safety specifications updated. ☐ "Feels-like" usability data collected.

Appendix A - Health Innovation Client Journey Map

Client Journey	Product-Market Fit	Business Readiness	Regulatory Compliance	Product Development
Scaling	☐ Real-world trial conducted and validated economic data and endpoints achieved. ☐ Training materials & support established. ☐ Peer reviewed data from efficacy trials published.	☐ Series A investment secured. ☐ Sales and support team established ☐ First-buyer secured. ☐ Reimbursement for associated product and/or services listed.	☐ Company registered with applicable regulatory agencies. ☐ Quality System documentation completed for GMP-manufacturing processes.	☐ "Looks-like" "Works-like" "Feels-like" product finalized. ☐ Patents issued.
Establishing	☐ Solution included in local clinical practice guidelines ☐ Peer reviewed data from real-world trials published.	☐ Series B investment secured ☐ Profitable business venture with sustainable sales funnel and recurring revenue. ☐ Scale-up plan in place and new markets launched.	☐ Regulatory agency monitoring and inspections conducted.	☐ Improvement plan based on feedback from stakeholders drafted.
Leading	☐ Recommended practice by medical specialty supported by peer-reviewed data.	☐ Dominant market share (≥30%).	☐ Obsolescence planning.	☐ Obsolescence planning.
AI Client Journey	**Product-Market Fit**	**Business Readiness**	**Regulatory Compliance**	**Product Development**

Map provided by Alberta Innovates