Women's Health Medical Pathway



Program Guide



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1. Women's Health Medical Pathway (wHealth MedPath) Program

Through an investment from the National Research Council of Canada Industrial Research Assistance Program (NRC IRAP), Innovation Factory in partnership with Femtech Canada established the **Women's Health Medical Pathway (wHealth MedPath)** program.

wHealth MedPath aims to address the opportunities of the emerging femtech health and wellness cluster by supporting startup and scaling firms developing novel femtech products and services. Collaborating with physician networks, physician investment groups, and private-sector organizations, the wHealth MedPath program operates a suite of services focused on knowledge transfer, connections with key opinion leaders, and tangible deliverables that advance product development and timelines around go-to-market.

Successful collaborations will accelerate commercialization efforts, enabling femtech firms to develop key items such as; intellectual property, obtain path-to-market reports, develop regulatory strategy or quality management systems or undertake key product development and evaluation. These insights will support the development of crucial documentation needed to advance commercialization milestones (i.e. collaborative projects with world-class hospitals and clinicians, FDA and/or Health Canada approval, market-ready product development etc.).

Through the wHealth MedPath program, Canadian femtech firms can leverage \$5,000 of non-dilutive funding to connect with physician networks or physician investment groups on market readiness, product positioning, business strategies, product viability and product feasibility. Leveraging the feedback received from physician networks or physician investor groups, firms can then unlock up to \$15,000 of non-dilutive funding to collaborate with one of our partner private sector CROs or CDMOs. Applying femtech firms will need to provide a minimum cash match of 50% of the awarded funding to work with our CRO or CDMO partners.

wHealth MedPath applicants must meet the following criteria to be eligible:

- A privately incorporated Canadian femtech firm¹;
- Working towards commercializing an innovative technology at Technology Readiness Level Six (TRL-6: System/subsystem model or prototype demonstration in a simulated environment) or above;
- Demonstrated commitment to commercializing innovation with a clear women's health application;
- Femtech firms must be an active member of Femtech Canada. Applications can be found <u>here</u>; and
- Ontario based femtech firms must be a client of Innovation Factory. Firms can sign-up for free with Innovation Factory <u>here</u>. (please note this requirement is not applicable to firms based outside of Ontario)

¹Femtech: Technology including products, services, diagnostics, and software addressing health and wellness concerns that solely, disproportionately or differently affect women, girls, non-binary folks, trans people, and those assigned female at birth.





The wHealth Medpath program operates under a rolling application intake process. Firms are invited to apply by filling out an application at: <u>https://femtech.ca/whealth-medpath/</u>. Applications will be accepted until March 31, 2026, or until program funds have been fully committed.

If you have any questions please feel free to contact the wHealth MedPath team at <u>lifesciences@innovationfactory.ca</u>.



2. wHealth Program Stakeholders: Innovation Factory, Femtech Canada, and NRC IRAP

2.1 Femtech Canada

wHealth MedPath

Publicly launched in 2024, Femtech Canada is a national coalition whose mission is to transform health outcomes for women in Canada and globally by fostering innovation, commercialization, and investment in women's health technologies. Femtech Canada has convened a thriving community of over 180+ femtech firms. These firms are focused on addressing critical health concerns that directly (e.g., menopause, pregnancy, reproductive health) and disproportionately or differently (e.g., mental health, autoimmune disorders, cardiovascular diseases) affect women and those who identify as women.

Femtech Canada's work includes:

- Ecosystem: Develop and strengthen the national capacity of the femtech network to enable a thriving cluster;
- Education and Advocacy: Shift the system to close gaps in women's health outcomes and gender equity; and
- Programs: Deliver transformational initiatives that enable femtech firms to scale and grow.

Femtech Canada is operated by Innovation Factory. Learn more at: <u>www.femtech.ca</u>.

2.2 Innovation Factory

Innovation Factory (iF) is a non-profit business accelerator, providing entrepreneurs with business services, training, mentorship, and strategic connections to help bring your disruptive technologies to market, increase revenues, attract investment, and create jobs.

Serving as the catalyst for tech innovation in the greater Hamilton area since 2011, we are driven to support:

- Entrepreneurs bringing new ideas to life and to market;
- Small or Medium Enterprises (SMEs) getting to the next level; and
- The Southern Ontario ecosystem to build a dynamic culture and a community of innovation.

Innovation can happen anywhere. Our goal is to make it work everywhere. We work to elevate key industry sectors including life sciences & healthcare, advanced manufacturing, clean tech, information technology, integrated mobility and social innovations.

Learn more at: <u>www.innovationfactory.ca</u>.









2.3 National Research Council Industrial Research Assistance Program (NRC IRAP)



The National Research Council Industrial Research Assistance Program (NRC IRAP) is a Canadian government initiative that supports the innovation and growth of small and medium-sized enterprises (SMEs). It provides financial assistance, advisory services, and technical expertise to help businesses develop and commercialize innovative technologies. By connecting SMEs with Industrial Technology Advisors (ITAs), IRAP offers guidance in research and development, market expansion, and commercialization strategies. With its extensive network and resources, the program aims to accelerate the competitiveness of Canadian firms, fostering innovation and job creation, and helping businesses scale their operations in both domestic and international markets.

Through NRC IRAP's mandate of stimulating wealth creation through Canadian Innovation, NRC IRAP has been successful in the mission to be accelerate of accelerating the growth of SMEs by providing a comprehensive suite of innovation services and funding including:

- Providing value-added frontline service to clients;
- Respecting and investing in the value of people;
- Building and contributing to partnerships;
- Maintaining and enhancing technical credibility; and
- Ensuring accountability for quality service and effective use of resources.

Learn more at <u>www.nrc.canada.ca/en/support-technology-innovation.</u>





3. wHealth MedPath Program Overview

3.1 – wHealth MedPath program objectives

wHealth MedPath aims to expedite commercialization efforts to develop novel technologies that can provide a diverse set of evidence based women's health and wellness products to key areas of health such as autoimmune health, brain and mental health, breast health, cardiovascular health, fertility, urology, general health, longevity, gerontology, gynecological and pelvic health, hormone health, LGBTQ+ health, maternal health, menopause, menstruation, minority women's health, reproductive health and contraception, and sexual health.

3.2 - wHealth MedPath program activities

wHealth Medpath connects femtech firms with key opinion leaders for feedback which can be used to inform work with CDMOs and CROs to produce crucial documentation and accelerate commercialization timelines of femtech firms. Through wHealth MedPath, femtech firms develop relationships, acquire critical knowledge, and create tangible documentation with clinicians and specialists to support their commercialization efforts. The specific scope of activities conducted through the wHealth MedPath program are agreed upon on a project-by-project basis, based on the needs of the applying firm.

3.3 – Who can apply?

Canadian women's health firms can apply to participate in wHealth Medpath, subject to the following minimum criteria:

- A privately incorporated Canadian femtech firm²;
- Working towards commercializing an innovative technology at Technology Readiness Level Six (TRL-6: System/subsystem model or prototype demonstration in a simulated environment) or above;
- Demonstrated commitment to commercializing innovation with a clear women's health application;
- Femtech firms must be an active member of Femtech Canada. Applications can be found <u>here</u>; and
- Ontario based femtech firms must be a client of Innovation Factory. Firms can sign-up for free with Innovation Factory <u>here</u>. (please note this requirement is not applicable to firms based outside of Ontario)

Please note that while all firms that match the above criteria are encouraged to apply, final program acceptance will require a positive recommendation from the program funder NRC IRAP. This is obtained through an assigned NRC IRAP ITA. If you do not have an ongoing relationship with NRC IRAP the wHealth MedPath team can support you in connecting with them.

²Femtech: Technology including products, services, diagnostics, and software addressing health and wellness concerns that solely, disproportionately or differently affect women, girls, non-binary folks, trans people, and those assigned female at birth.





3.4 - What is wHealth MedPath offering?

Applicants to the program have the option of applying to two levels within the wHealth MedPath program:

Level 1 is a product market assessment conducted by a physician network or a physician investment group. This will connect applicants with clinicians or specialists in their field of focus, to understand and highlight areas of strength and opportunities for improvement.

The product market assessment will review and provide tangible feedback on a number of critical areas for business commercialization including but not limited to:

- Market Assessment;
- Clinical Impact;
- Regulatory and IP considerations;
- Sex and Gender Lens;
- Reimbursement Landscape; and/or
- Patient-Centred Design & Engagement.

Upon successful conclusion of a Level 1 project, firms will be considered for participation in a Level 2 project.

Level 2 provides applicants with access to a service based commercialization project with a contract design and manufacturing organization/contract research organization (CDMO/CRO). The scope of the commercialization project may be informed by the feedback received from product market assessment conducted in Level 1 and must be identified by the applying firms in coordination with one of the CDMO or CRO partner organizations. The wHealth MedPath team will attempt to match high potential applications to a relevant CDMO/CRO but applicants can list their preference.

Examples of potential Level 2 commercialization projects include:

- Product Design & Testing (Journey Mapping, Assumption Mapping, Product Development, Regulatory Strategy & Submissions, Cybersecurity Testing etc.);
- Product Documentation (Path-to-Market Reports, QMS, Clinical Study Design etc.); and
- Digital Product Support (Prototype Development, Cybersecurity Hardening, Advanced API & Data Integration etc.).

Please note that while most applying firms will need to complete Level 1 before completing Level 2, in select instances femtech firms that wish to only access Level 2 funding may be accepted into the program at the discretion of the wHealth MedPath team. The applying firm must be of sufficient maturity and be able to demonstrate market fit to the wHealth MedPath team.

3.5 – What funding is available?

Applying firms can access up to:

- \$5,000 (inclusive of HST) can be used to support Level 1 product market assessments; and
- Up to \$15,000 (inclusive of HST) can be used to support Level 2 CDMO/CRO commercialization projects.
 - Firms must provide a 50% cash match.





3.6 Considerations on use of government funding as cash match

When applying to a government funded program there are certain considerations that apply. Please note that:

- Applicants must declare any other sources of government funding received within the 12 month period prior to the application process;
- Stacking of federal government funding is not allowed; and
- Stacking of provincial and municipal funding is subject to review and approval.

3.7 – What costs are eligible?

Innovation Factory will reimburse the physician network or physician investment group up to \$5,000 at the completion of the product market assessment. Reimbursement is subject to the completion of an attestation that all work has been performed, and a final report that describes the impact of the assessment and future plans for collaboration or investment.

Innovation Factory will reimburse the CDMO/CRO up to \$15,000 as laid out in a payment plan drafted on a project-by-project basis. Reimbursement is subject to proof of applying firm cash match, completion of an attestation that all work has been performed, and a final report that describes the impact of the project and future plans for commercialization.

Project costs are subject to approval by the wHealth MedPath team and must be auditable. If you have questions about eligible costs, please reach out to the wHealth MedPath program team for more information.

3.8 - Who are the delivery partners?

wHealth MedPath program team has identified physician networks, physician investment groups, and CDMO/CRO delivery partners to facilitate the execution of wHealth MedPath, based on their expertise, facilities and capabilities. the five delivery partners wHealth MedPath is collaborating with to support femtech firms are:

Physician Network and Physician Investment Group Delivery Partners:

- <u>HaloHealth</u>: Physician angel investment group that provides specialty match advisory, healthcare connections and capital to early stage healthtech ventures. HaloHealth holds offices in Toronto, Calgary and Vancouver; and
- <u>MACcelerate</u>: Run out of McMaster University Michael G. DeGroote Medical School Waterloo Regional Campus, MACcelerate helps startups bridge the clinical gap between ideas and access to the medical expertise, cutting-edge innovation resources and a network of top clinicians and researchers required to scale and grow.





CDMO/CRO Delivery Partners:

- <u>Avania CRO</u> a contract research organization offering end-to-end solutions inclusive of strategic consulting and product development, data analytics and safety compliance, clinical operations, and market access and reimbursement;
- <u>Tristar</u> an innovation and development studio offering comprehensive services for femtech startups inclusive of fractional CIO, CPO, and CTO services, custom app development, infrastructure development, website development, and business as usual support; and
- Inertia Product Development handles every step of the medical device development process - from distilling the patient's needs and the caregiver's problems, to assessing risk and product verification, to shipping finished products to customers.





4. wHealth MedPath Program Process

<u>4.1 – wHealth Medpath process</u>

Participation in wHealth MedPath occurs in eight (8) key steps, including:

- <u>Step 1 Application</u>: Applicant completes wHealth MedPath application <u>form</u>.
- <u>Step 2 Screening and Level Identification</u>: wHealth MedPath program team reviews the application and schedules an introductory meeting to explore project suitability and alignment. Applicant's eligibility for Level 1 and/or Level 2 is determined and assigned by the wHealth MedPath program team.
- <u>Step 3 NRC IRAP Eligibility</u>: Applicant and wHealth MedPath program team meet with the applicant's NRC IRAP Industry Technology Advisor (ITA) to secure a recommendation to participate in wHealth MedPath. Should the applicant not have an assigned NRC IRAP ITA, the wHealth MedPath team will work with the firm to connect them to NRC IRAP to explore eligibility.
- <u>Step 4 Alignment with Delivery Partner Capabilities:</u> The wHealth MedPath program team works with delivery partner(s) to determine capacity and alignment of capabilities to help initiate a wHealth MedPath project.
- <u>Step 5 Contracting</u>: Applicant works with wHealth MedPath delivery partner to complete a wHealth MedPath contract to define the scope of work, deliverables, and milestones for the engagement. Once complete the contract is reviewed by the wHealth MedPath team and tri-laterally executed by the applicant, delivery partner and Innovation Factory.
- <u>Step 6 Execution</u>: Working together, the delivery partner and applicant perform the activities described in the scope of work.³
- <u>Step 7 Close Out:</u> Delivery partner submits an attestation of work completed and a final report, signed by both the delivery partner and applicant, to the wHealth MedPath program team. These documents confirm all deliverables and milestones have been successfully completed. Applicant participates in an exit interview session with the wHealth MedPath program team, Femtech Canada and NRC IRAP representatives to explore potential opportunities for additional support or collaborative projects through NRC IRAP and the Femtech Canada Network.
- <u>Step 7 Reporting</u>: wHealth MedPath program team socializes the final report and attestation of completion of work to the applicant's NRC IRAP ITA and the NRC IRAP program sponsor to report on program outcomes and potential next steps. The wHealth MedPath team will follow up with both delivery partner(s) and firm one and two years after project completion to measure success of the program and report back to the program funder, NRC IRAP.

4.2 - Program deadlines and timelines

Applications will be accepted on a rolling basis. Project grants for this program will be approved until March 31st, 2026, or until all funds have been committed.

³ Please note that if the applicant is participating in both a Level 1 and a Level 2 engagement they will need to complete steps 5 and 6 twice. Once with a physician network or investment group delivery partner and once with a CDMO/CRO delivery partner.





5. Program Administration

5.1 – Project contracts

A signed project contract, outlining the scope of work and activities to be performed, is required for every wHealth MedPath product market assessment (Level 1) and CRO/CDMO commercialization project (Level 2). contract templates have been created by Innovation Factory to expedite the contracting process.

- Timelines associated with each product market assessment and/or CRO/CDMO commercialization project will be scoped and agreed upon on a project by project basis; and
- Funding will be released on a reimbursement basis after the attestation of work completed and final report have been submitted by the physician network, physician investment group, and/or CDMO/CRO partner.

5.2 – Reporting requirements

wHealth MedPath grant recipients will meet with the wHealth MedPath program team on an *ad hoc* basis to provide an update on the project progress. A final report detailing the successful completion of the project(s) deliverables, an attestation of the work completed, and proof of firm match (as applicable to Level 2 projects) will be due at the end of the project(s). These reports will be submitted by the delivery partner in collaboration with the applicant. Reporting templates have been provided to facilitate this process.

The recipient will be asked to periodically report back to the wHealth MedPath program team up to two years following the completion of the project(s), including basic firm performance data required to measure the success of the program.

5.3 – Protection of intellectual property

Coverage and treatment of intellectual property (IP) generated through the execution of a wHealth MedPath CRO/CDMO project will be aligned with the Innovation Factory IP Policy (available upon request).

Applicants should clearly mark as "proprietary" any information within their application or within the drafted protocol documents that they deem to be a trade secret or proprietary information. Proprietary information can include details regarding the applicant(s), their financial information, and their project. This information is to be maintained as confidential and will not be shared on public sites. Proprietary information found within applications will be used or disclosed only for the purposes of delivering the mHealth MedPath program.

5.4 – Becoming a member of Femtech Canada

All applicants are required to join the Femtech Canada network to participate in this program. Femtech Canada is a free, national network that will provide ongoing support to applicants beyond the parameters of the program. Companies can join the Femtech Canada network <u>here</u>. Key benefits of the network include:

- National peer to peer support
- Access to industry partners and investor
- Specialized programming and events
- Brand amplification through social media, newsletter and public database





5.5 – Becoming a client of Innovation Factory

As the wHealth MedPath program is operated by Innovation Factory a requirement for participation in the wHealth MedPath program is that all Ontario headquartered applicants become a client of Innovation Factory.

As a client of Innovation Factory participants unlock our innovation advisory services delivered by our Venture Growth team. In addition to accessing non-dilutive funding opportunities like wHealth MedPath, clients of Innovation Factory receive mentorship services, support building strategic connections, and access to training opportunities, all free of charge.

Please fill in the Client Intake Form found here.

Once Innovation Factory receives this form from you our Venture Growth team will make contact with you for an initial meeting so that we can best tailor our services to the exact needs of your business.

5.6 – wHealth MedPath team contact information

If you have any questions, please feel free to contact the wHealth MedPath team at <u>ifesciences@innovationfactory.ca</u> or visit our website at <u>https://femtech.ca/</u> and check out our FAQs. Alternatively, please feel free to call us on our general line at 905-667-2611.

Visit us at our Hamilton Regional Office located at: B21 - 175 Longwood Road South, Hamilton, ON L8P 0A1 Canada; or

Visit us at our Halton Regional Office located at: 801 - 5500 North Service Road, Burlington, ON L7L 6W6 Canada.





6. Supplementary Information

6.1 – Access to Information Act and the Privacy Act

The wHealth MedPath program is subject to the federal Access to Information Act and Privacy Act.

6.2 – Underrepresentation balance (EDI)

Femtech Canada and Innovation Factory encourage the participation and engagement of femtech firms from underrepresented groups to encourage diversity among wHealth MedPath program grant recipients.

