



TRANSFORM HF

The Digital Hub User Guide

September 2024

The Digital Hub:

Bringing great ideas out of the lab

ABOUT US

The [Digital Hub](#) is the research translation arm of [TRANSFORM HF](#), an initiative dedicated to advancing equitable access to heart failure care through digital innovation. Our mission is to bridge the gap between laboratory research and real-world application for researchers and companies developing novel digital cardiovascular health technologies to accelerate research translation and improve patient outcomes.

Embedded within Canada's largest hospital network and most multicultural city, the Digital Hub offers unparalleled access to world-class expertise and a diverse patient population. Our team's deep understanding of the healthcare landscape – including the needs of patients, clinicians, and the system – ensures that your innovation has the support and environment necessary to thrive.

We leverage our unique position to enable researchers and companies to:

- Tap into a rich and deeply **integrated network** of clinicians, patient partners, and researchers spanning academic and hospital institutions.
- Access critical data and conduct rigorous **testing in a real-world setting** to ensure innovations meet the highest safety and efficacy standards.
- Apply a **health equity** lens and engage with patient partners to ensure solutions are accessible and beneficial to all.

Whether you're developing a new diagnostic tool, a therapeutic device, or a remote patient management platform, the Digital Hub can help you navigate the complexities of healthcare innovation – from initial concept through to successful implementation. It's our goal that your technology gets off the lab bench and into user's hands, ensuring a genuine and meaningful impact on patient care.

Did you know that it takes an average of 17 years for an innovation to move from research to practice¹?

The Digital Hub seeks to accelerate research translation to get innovative solutions to those who need them most.

¹Morris ZS, Wooding S, Grant J. The answer is 17 years, what is the question: Understanding time lags in translational research. *J R Soc Med.* 2011 Dec;104(12):510-20. doi: 10.1258/jrsm.2011.110180. PMID: 22179294; PMCID: PMC3241518.

OUR SERVICES

Our team can customize services to your needs: end-to-end support, a-la-carte services, or anything in between. It's our priority to deliver high-quality services that maximize the value of your investment – that's why the Digital Hub operates on a cost-recovery model. Our team will work with you to develop clear pricing structures that align with your goals at project outset.

See some of the services we offer below.

Clinical Validation



We offer unparalleled access to clinical validation services, allowing you to rigorously test your innovative digital health technologies against established gold standard devices.

Our partnerships with leading healthcare institutions, such as UHN, ensure that your technology is evaluated in real-world clinical settings, providing robust data and insights.

Clinical Trials



From the initial design phase to the final deployment, our team provides comprehensive support to ensure your clinical trials are conducted with precision and adhere to regulatory standards.

We collaborate closely with you to develop protocols that optimize your digital health technology, while ensuring efficient data collection.

Data Management & Analysis



Our Data Management service ensures that your clinical and research data is collected, stored, and analyzed with the highest levels of efficiency and security.

We work with REDCap, an electronic case report form platform, to provide secure data handling in compliance with relevant privacy regulations. Additionally, we are proud to offer advanced analytical services through a partnership with the Ted Rogers Computational Program.

Patient Engagement



Our unique Patient Engagement service allows you to access our extensive and diverse network of active cardiovascular patient and caregiver partners, ensuring that your digital health projects are grounded in real-world experiences.

At the Digital Hub, we believe that acknowledging and integrating patient experience leads to more comprehensive and inclusive outcomes. That's why we provide expert guidance on patient engagement, collaboration, and compensation to enhance the relevance and impact of your research.

Regulatory & Compliance



We provide essential support to help you understand and navigate the complex landscape of regulatory requirements.

We assist in the preparation and compilation of regulatory documentation for investigators, ensuring that your digital health technology and clinical trials meet the standards set by the relevant regulatory and governing agencies.

Ethics Navigation



The Digital Hub is dedicated to ensuring that all research involving human participants, biological materials, or secondary data complies with the highest ethical standards, including TCPS 2 and ICH-GCP principles.

We guide researchers and companies through the complex process of obtaining Research Ethics Board approval, including assisting with applications, informed consent forms, and protocol amendments. Additionally, for studies involving UHN resources or patients, we manage the institutional approval process, ensuring all necessary assessments and approvals are completed efficiently to facilitate the start of your research.

Laboratory Investigation



The Digital Hub has an official partnership with the Core Laboratory within the University Health Network's Laboratory Medicine Program. This partnership enables unparalleled access to state-of-the-art instrumentation for cardiac marker, tumor marker, endocrinology, transplantation, immunology, and point-of-care testing.

Through the Digital Hub, users can access these advanced laboratory services and seamlessly integrate them into their research workflow.

OUR PROCESS

We recognize that every research project is unique – that’s why we tailor our approach to meet each user’s specific needs. However, we’ve provided a general overview of the key milestones to help you begin to envision your roadmap to success...

Step 1: Intake Form

Users complete an online intake form. This form helps you articulate essential information, such as your project's goals, the digital health technology involved, and any specific needs or challenges you anticipate. Once you submit the form, a member of our team carefully reviews your information. We will then schedule an initial consultation to ensure we fully understand your objectives and how best to support you in transforming your vision into reality.

Step 2: Initial Consultation

You’ll meet with our team to discuss the details provided in the intake form and dig deeper into your specific needs. Our experts will offer scientific, clinical, and logistical insight and recommendations. This session allows us to gain a comprehensive understanding of your project and the context in which your digital health technology will be developed and deployed. Following this discussion, we assess the necessary resources and outline the best strategies for success.

The initial consultation is one hour and free of charge. Ongoing consultations will be integrated into your project workflow as needed.

Step 3: Clear Agreement

Following the initial consultation, our team prepares a formal agreement tailored to the specifics of your project. This document details key aspects such as pricing, timelines, and intellectual property rights, ensuring all elements are clearly defined. The agreement is designed to align expectations and provide a solid foundation for our partnership. Additionally, further agreements may be required between you and the University Health Network, such as Material and Data Transfer Agreements, commercialization, and fund transfers.

Step 4: Collaborative Study Design

In this phase, our clinical, scientific, and research leads and patient and caregiver partners work closely with you to align study design to project objectives. Through a collaborative and efficient refinement process, we ensure your study addresses critical aspects such as health equity, clinical relevance, feasibility, impact, and scalability. Alongside study design, the Digital Hub assists in developing essential study materials, including informed consent forms, case report forms, and adverse event logs. Additionally, we provide full service in managing the Research Ethics Approval and Institutional Authorization process.

Step 5: Service Delivery

Once all parties are satisfied with the study design, we can implement your study! From participant identification and recruitment to data collection and analysis, the Digital Hub ensures that every aspect of your study is executed with precision. Our team collaborates closely with the clinical care team and research staff, providing continuous support throughout the process. Leveraging our expertise and resources, we closely monitor progress and maintain open communication with you, offering regular updates.

This phase is where your innovation begins to take shape in the real world, paving the way for maximal impact and successful integration into clinical practice. Congratulations!

KEY CONSIDERATIONS

Our team looks forward to discussing your project! Before you reach out, here are some things to consider:

- What is your digital health solution and why is it important?
- Who is the intended user of your digital health solution?
- How do you see your innovation integrating into healthcare delivery or self-management?
- What is the development stage of your digital health solution?
- How can the Digital Hub facilitate your success, and what services may you require?
- How would you like to engage patients in your project?
- Will you require space or equipment to run your project?
- Does your technology need Health Canada's Investigational Testing Authorization before it can be evaluated?

CONTACT US

If you're ready to hit the ground running, complete the [Intake Form](#)!

To learn more about working with the Digital Hub, contact Ben Kim (ben.kim@uhn.ca).

The Digital Hub program adheres to the highest standards of clinical research, including compliance with ICH-GCP (International Council for Harmonisation – Good Clinical Practice), TCPS 2 (Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans), and the policies of UHN (University Health Network). The Digital Hub is committed to creating a research environment conducive to patient-oriented research. We strongly recommend and incorporate the guidelines set out by the Patient Appreciation Policy of TRCHR (Ted Rogers Centre for Heart Research). Our commitment to these guidelines ensures the ethical and responsible conduct of all studies under our purview.