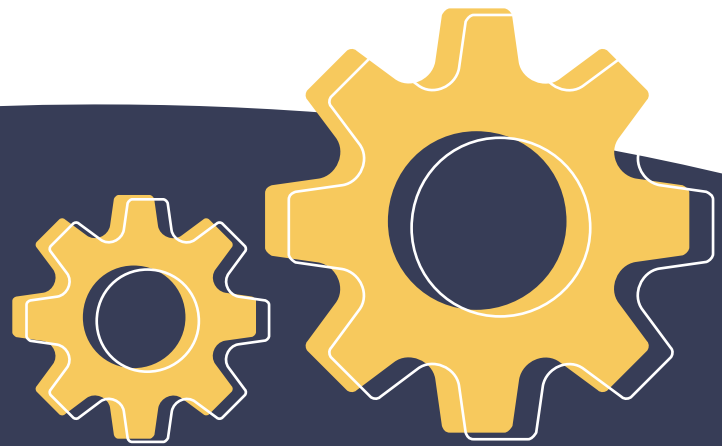




RESEARCH INSTITUTE
INSTITUT DE RECHERCHE



National Health-Tech Innovation Conference

Presented by CHEO Research Institute's
Innovation Core

Digital Tool Kit

2023

Thank you for attending the inaugural National Health-Tech Innovation Conference on December 1st, 2023.

This sold-out event was a huge success. The day was filled with thought-provoking, inspiring, and change making discussions. Our speakers and session leaders did a remarkable job at connecting our three core audiences – Healthcare, Research, Business – through showcasing real-life examples of challenges as well as ways to successfully communicate, collaborate, and foster relationships between stakeholders. The goal being to help enhance how we innovate solutions in the healthcare sector.

As a take-away, we are providing you with a digital toolkit to enhance your conference experience. Below are some session highlights, key learnings and supplementary resources that can be leveraged and applied to your respective roles and organizations.

View the official Conference [program here](#).

[Watch and Share the Event's Sizzle Reel.](#)



Enhancing Innovation Adoption through Empathy and Understanding

If you're an innovator from outside the healthcare system, think about some things that are important to the researchers and the healthcare workers that may not be directly relevant to you:

1

Priorities and Timing.

Learn about what else is going on. Budget approvals, re-orgs, big EHR implementations, other big initiatives that will consume the oxygen required to work with you.

2

Privacy and Security.

A basic foundation of privacy and security is non-negotiable. Make sure that you've addressed all the areas that are required, and speak up if you think that an organization is adding more hoops/barriers than the rules require in an effort to be 'extra safe'.

3

Procurement. Understand the perspective of each person you're dealing with. Do they care if the innovation works? Will they get in trouble if it doesn't? Will they get in trouble if they drag their feet?

If you work inside the healthcare system, there are some things to keep in mind about the priorities of small companies.

1

Speed/Fundraising: Most startups need to raise outside capital. By moving quickly with contracting and early-stage projects, you allow companies to raise additional funds that will help them to provide you with more value. Startups usually have only 18 months of funding remaining.

2

First customer. Usually the biggest value that an early customer can provide to an early stage venture is a proof point. This will almost always be more valuable to the company than the money you pay them.

3

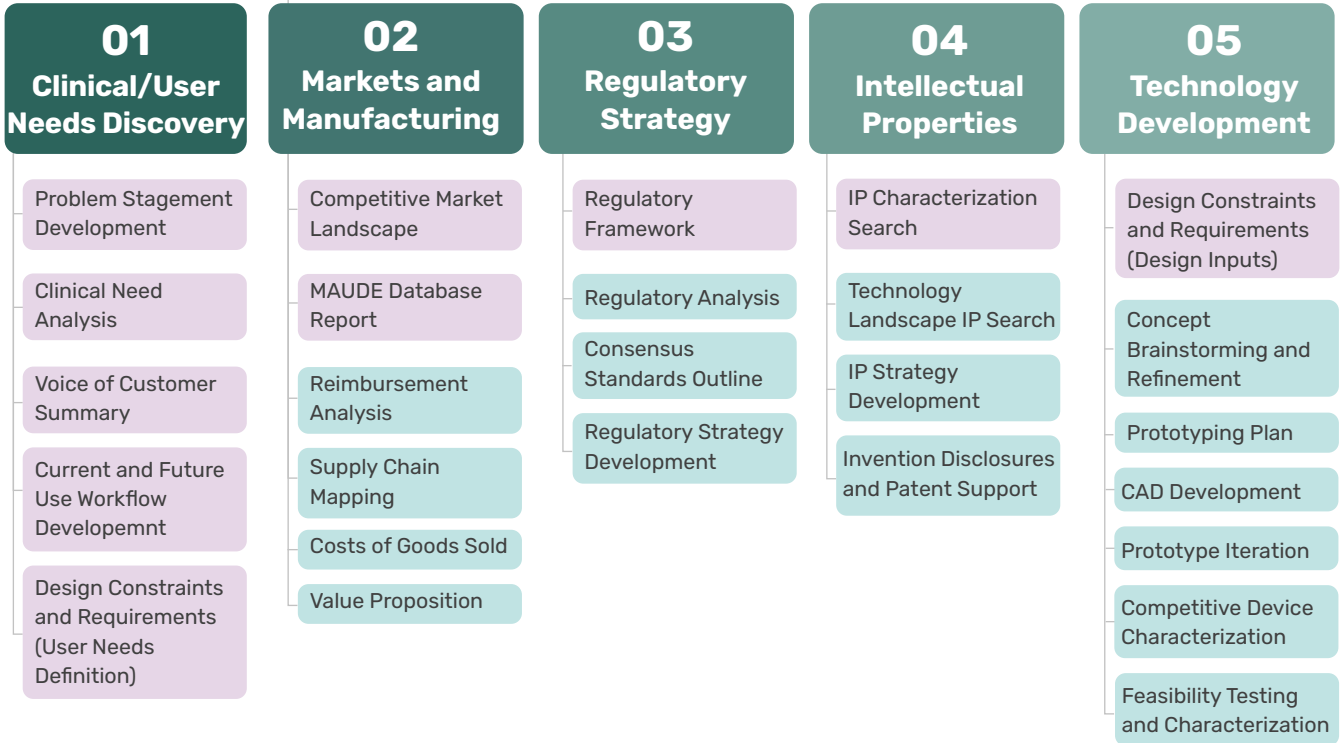
Learning by doing. It's worthwhile to remember that people may be doing things for the first time, and may not understand the system as well as you do.

In general, if all parties could look ahead to the next few steps of the process and understand who needs to do what, there would be more progress and fewer headaches.

Where to Begin: Guiding Steps for Phase '0'

Phase zero process is a holistic, evidence-based approach to early-stage device development that outlines important factors that help drive strategic decisions.

● Post solution ideation ● Pre solution ideation



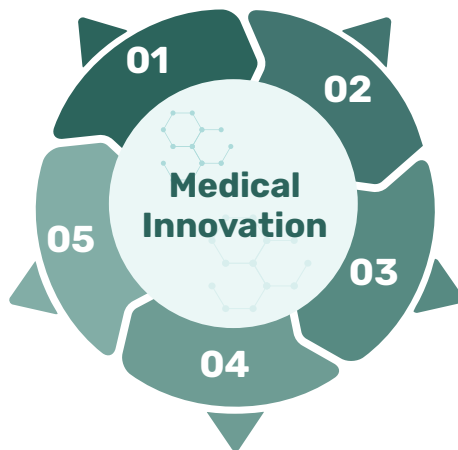
Business Strategy Development

Clinical Needs Assessment:

- Engage with healthcare pros and stakeholders.
- Analyze disease data, treatment gaps, and remain open to diverse solutions.

Technology Development:

- Define specs.
- Brainstorm solutions.
- Collaborate for product excellence.



Intellectual Property:

- Conduct patent search.
- Plan IP creation and filing.
- Prioritize unique solutions.

Market Analysis:

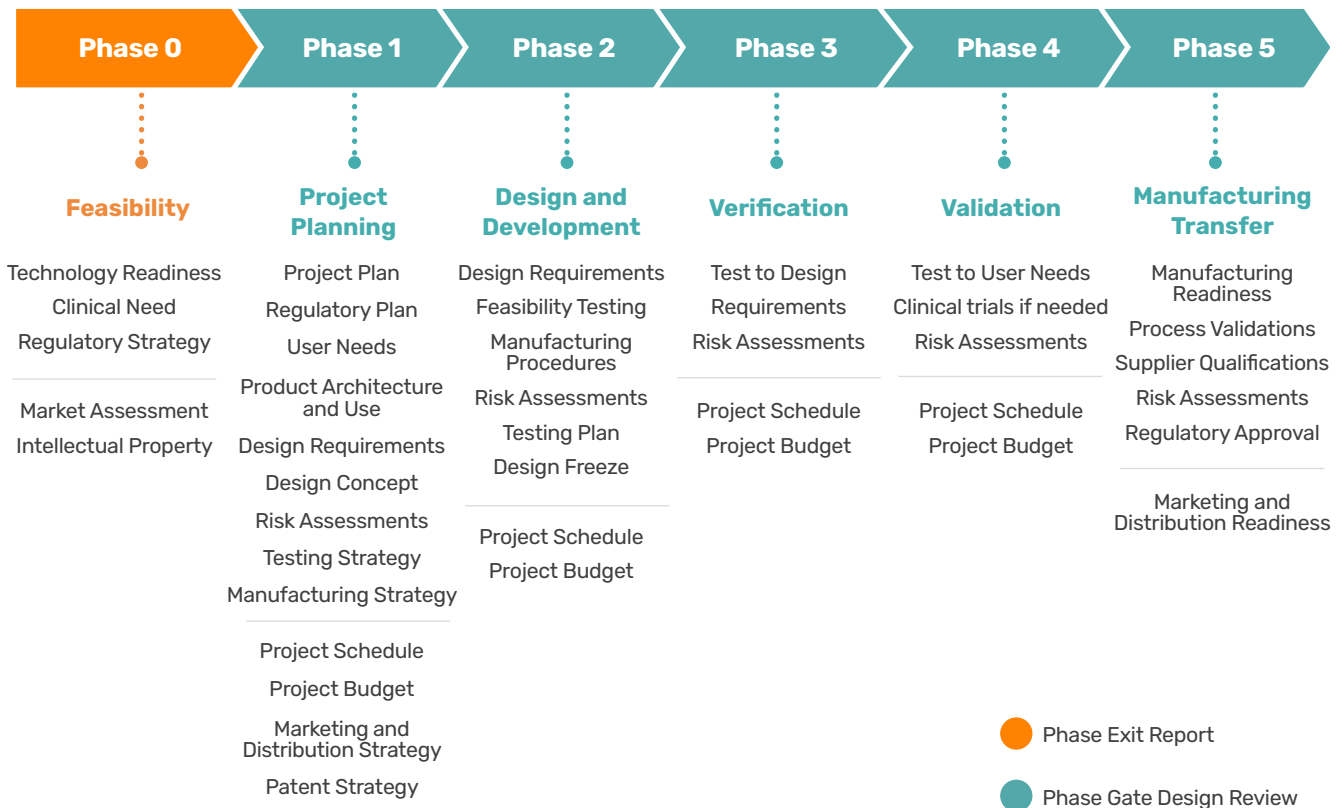
- Research market segments.
- Assess size, trends, competitors, and gaps in solutions.

Regulatory & Reimbursement:

- Identify regulatory pathways.
- Understand clinical trial and reimbursement requirements.
- Ensure affordability for users.

Design Control Process: Planning out Product Development

The following are key steps in the medical device Design Controls process. Prior to this, the design should be prototyped extensively to ensure that it is viable and to prove willingness to adopt by the target market.



Navigating the need for “Profit” in the Healthcare Lexicon

Learn

Ethical Balancing Act

- ◆ Understand the ethical considerations in profit-driven innovation.
- ◆ Learn about the Conflict-of-Interest policy at your institution.
- ◆ Explore collaborative approaches between healthcare professionals and innovators to maintain public trust.



Real-World Insights

- ◆ Study examples of challenges and opportunities arising from the coexistence of publicly funded healthcare and private business interests.
- ◆ Extract lessons for navigating the complexities of the healthcare industry.



Plan

Effective Integration Strategies

- ◆ Develop strategies for effective integration of commercialization into healthcare.
- ◆ Find a mentor and develop a business plan.
- ◆ Focus on practices discussed by the panelists to benefit both patients and stakeholders.



Navigating Conundrums

- ◆ Plan for potential conundrums in the pursuit of healthcare innovation intersecting with commercialization.



Do

Profit and Patient Care Balance

- ◆ Implement a balanced approach between profit-driven innovation and the primary goal of improving patient care.
- ◆ Act on insights provided by Panelist 5 to ensure innovations positively impact both financial and healthcare outcomes.



Collaborative Initiatives

- ◆ Initiate collaborative efforts within your professional network to further discuss and implement your innovations
- ◆ Disclose any conflict of interest with your organization but don't be afraid to engage.
- ◆ Share and disseminate knowledge gained to contribute to a broader understanding within the healthcare community.



Hitting Challenges Face on as an Innovator



Culture of Innovation

Traditional healthcare systems can stifle new ideas. To thrive, foster a culture of innovation that welcomes and refines new concepts.



A Strategic Approach

Instead of directly challenging norms, opt for nuanced methods like incremental innovation. Understand healthcare complexities and find strategic entry points for change.



Learning from Experience

In healthcare innovation, repeating failed strategies is counterproductive. Embrace a culture of continuous learning, using past failures as valuable insights.



High Attrition Rate

Healthcare innovation is risky. Be prepared for setbacks due to regulations, market dynamics, or unforeseen challenges. Resilience and adaptability are key.



Value Capture

When innovation succeeds, act quickly to maximize its benefits. Scale, secure IP rights, or form partnerships to stay ahead in the competitive healthcare landscape.



Thank you to our Contributors!

This toolkit was made in collaboration with our conference speakers and presenters.

We encourage you to connect with one another, to help bridge gaps and extend your network of innovators.

WELCOME PANEL and opening remarks



Matthew Bromwich



Nick Quain



Jason Berman



Blake Daly

PANEL Mistakes, Misunderstandings & Mistrust: Solving the Innovation Language Breakdown



Mitch Robinson



Anna McCormick



Hanu Chaudhari



Andrew Pelling

PANEL "Profit" In the Healthcare Lexicon



Stephen Ryan



Ron Johnson



Shawn Mondoux



Kate Woolhouse

PANEL Bringing Innovation to Life in Healthcare



David Hellwell



Jon Chatburn



Andrew Seely



Ashleigh Kennedy

WORKSHOP

Developing the
Innovation Mindset



Emily Blum



Ben Sprott

WORKSHOP

Innovation & Effective
Collaboration with
Hospitals and
Governments



Harvey Hawes



Cody Thompson

KEYNOTE

Tales from the
Trenches: Innovation
Success and Failures



Iain Hennessey

**CLOSING
REMARKS**



Matthew Bromwich



Jim Bottomley

About the Innovation Core

The Innovation Core at the CHEO Research Institute works directly with health start-ups, and CHEO researchers and clinicians to help solve long-standing problems that matter to children, youth and their families. We've developed a unique innovation pathway to trial ideas from health-tech companies at CHEO – to accelerate tangible solutions to market. Find out more about the Innovation Core at the CHEO Research Institute website. For information on future events, the Innovation program at the CHEO Research Institute, or to get involved, visit cheoresearch.ca/Innovation or reach out at Innovation@cheo.on.ca



References and Resources

The following are additional resources and supportive links to help with various phases and stages of Innovation.

Global Center for Medical Innovation “Book of Knowledge”

<https://gcmiatl.com/2021/06/08/ultimate-access-gcmis-medtech-innovation-book-of-knowledge/Guide-to-early-stage-medical-device-development-process>.

FDA Guidance Document - Design Control Process

<https://www.fda.gov/media/116573/download>
An overview of the entire Design Control system

FDA Guidance Document: Quality Risk Management

<https://www.fda.gov/media/167721/download>
Critical guidance for implementing risk management as an integral part of device design and development. Specifically, the sections in Annex I are extremely important to the design of a successful medical device.

FDA - How to Find and Effectively Use Predicate Devices

<https://www.fda.gov/medical-devices/premarket-notification-510k/how-find-and-effectively-use-predicate-devices>

Reimbursement: Whitepaper from NAMSA:

<https://namsa.com/resource/medical-device-reimbursement-strategy-how-to-plan-for-successful-market-commercialization/> (free registration required)

Classification: Whitepaper from Greenlight Guru

<https://www.greenlight.guru/blog/medical-device-regulatory-classification> (free registration required)

General Interview Tips

<http://vimeo.com/groups/204136/videos/75535337>

Market Considerations in Interviews

<http://vimeo.com/groups/204136/videos/75536337>

Stanford Biodesign Resources

<https://biodesign.stanford.edu/resources/learning.html>