

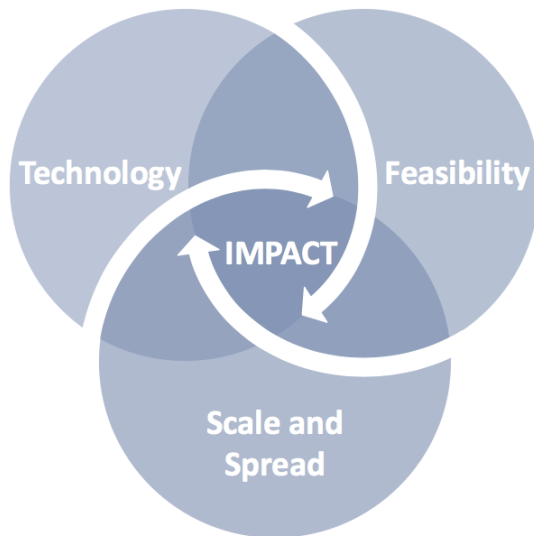
# Centre for Digital Health Evaluation

## Overview of CDHE Standardized Approach

	Standardized Considerations			
	Technology	Feasibility	Impact	Scale & Spread
<b>Evidence Gap</b>	Idea Regulatory requirements	HCP burden Pt/caregiver burden Institutional burden System burden	HCP benefit Pt/caregiver benefit Institutional benefit System benefit	Innovators Political/economic alignment
<b>Evaluation Metrics</b>	<b>Service Model Validation</b>		<b>Large Clinical Evaluation</b>	
	Usability  User experience	Tool, team, routine  Procurement (payer outcomes of interest)	Quadruple Aim outcomes (population health, cost, care and provider experience)  Equity	Replicability of service model in other settings  Transferability of outcomes across settings
<b>Questions that can be answered</b>	Does the tool perform its functions?  Is the tool easy to use?	Are the required changes to current practice feasible?  Is there impact on payer outcomes of interest?	Is there impact on the Quadruple Aim outcomes and equity?	Is there a sustainable business model?  Are the outcomes transferable to other jurisdictions?

## Standardized Evaluation Approach

This document outlines the guidelines by which the CDHE conducts a standardized evaluation approach for all projects. Uptake of digital health solutions is dependent on understanding the following:



1. *What* are the features?
2. *How* will we use it?
3. *Who* is going to buy it?
4. *Where* will it be adopted?
5. *Why* should we use it?

To address these questions, the Centre for Digital Health Evaluation (CDHE) uses an evidence-informed evaluation approach addressing four key domains: 1) the **technology** (*what* it does); 2) the **feasibility** (*how* it will be implemented and *who* might pay for it); 3) **scale & spread** (*where* it will be implemented); and 4) the **impact** (*why* it should be used) (Fig 1). The assessment of these domains is not static, and to ensure the sustainability of a technology, flexibility to change over time is

Figure 1. CDHE standardized evaluation domains.

required. Considerations of each domain in the context of sustainability is therefore core to evaluating digital solutions. The development of our evaluation approach was informed by several academic frameworks.<sup>1-5</sup>

### Step 1: Determining Evaluation Needs

**Problem definition:** What existing problem(s) is the solution attempting to solve? This must be considered from the perspective of all relevant stakeholders (i.e. clinical, patient, institutional, and/or system) and articulated according to the standardized evaluation considerations. Addressing this question will shape the interpretation of the needs assessment and subsequent scoping of the evaluation.

**Weaknesses or gaps:** What are the evaluation needs? Questions to consider include, for example: i) what evidence is missing; ii) are there changes to the routine or product that need to occur; and iii) are they targeting the right market? Table 1 lists considerations under each domain of the standardized evaluation framework to guide answering those questions.

Table 1. CDHE Evaluation Framework

Domain	Sub-domain	Considerations
Technology	Innovative solution	Mechanism, prior evidence/validation (through rapid literature review), innovativeness Problem statement
	Regulatory requirements	Safety, security, and privacy mitigations
Feasibility	Clinical	Workflow requirements, integration, behavioural changes
	Patient	Required engagement, education
	Institutional	Cost, training/HR requirements, risk
	Health System	Cost, policy requirements, risk

<b>Impact</b>	Patient	Health outcomes, experience, quality of care
	Health System	Cost-effectiveness, population health impact
<b>Scale &amp; Spread</b>	Political/ economic alignment	General interest or need, stakeholder alignment
	Innovator	Commitment, experience, skills, goals
	Procurement strategy	Marketing, potential revenue

## Step 2: Choosing an evaluation type

Figure 2 provides a suggested evaluation type based on where the weaknesses and gaps lie in existing evidence, as well as the maturity of the technology. This is a guideline, and at times may not be appropriate for the evaluation needs of a solution. Generally, selecting the appropriate evaluation will largely depend on the stage of development of the innovation.

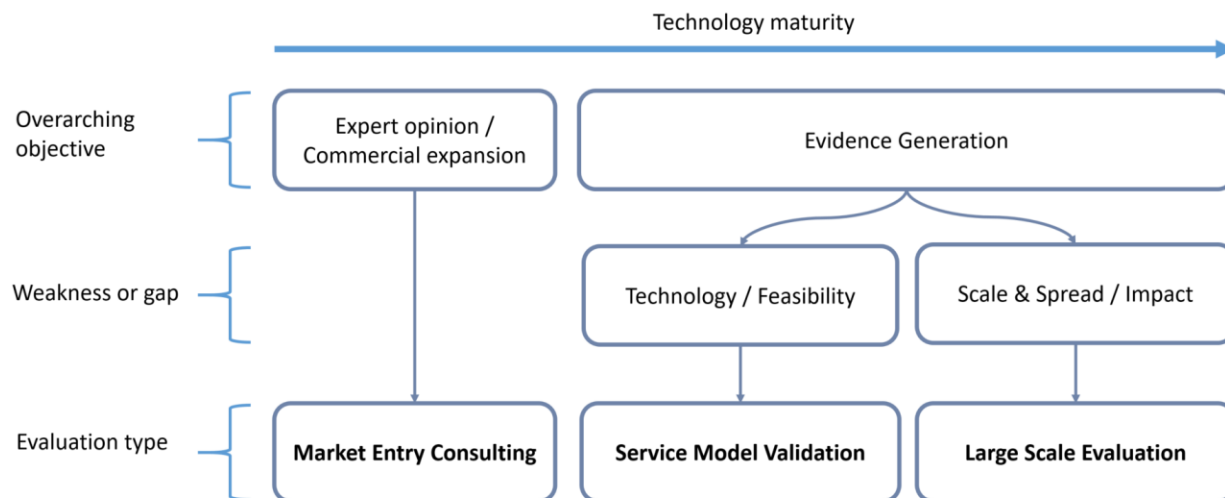


Figure 2. Evaluation selection tool.

## Step 3: Designing the evaluation

### A. Market Entry Consulting

This process is intended for early-stage companies seeking to develop an effective business model or clinical application within the constraints of the Ontario or Canadian health care system. We engage experts across four key domains (clinical, engineering/design, policy, and business development) to ensure companies establish a comprehensive foundation to inform future integration with the healthcare system. We assess the business model, the innovators, the health system impact (e.g. for patients, clinicians, and institutions), and policy and economic alignment (see the [CDHE Evaluation Framework](#) above). This service provides clients with streamlined feedback regarding their value proposition and economic viability within the Ontario healthcare system while also providing a mechanism for the early detection of promising digital health companies that are suitable for testing within the CDHE's broader service model.

### B. Service Model Validation

Service Model Validation involves understanding how a digital solution fits into a clinical model, what its potential effects are, and who will pay for it. This process consists of two primary steps:

- 1) **Research and Stakeholder Engagement:** Before evaluating a tool in a clinical site, we will map out the potential service models for that solution based on the [Tool, Team, Routine framework](#). This will be informed by a scan of the literature related to the clinical problem and any existing solutions. In collaboration with the client, we will generate 2-3 value propositions based on the proposed service model, and seek feedback from relevant stakeholders and potential users to refine the service model and value propositions.
- 2) **On-site testing:** Once a service model has been mapped out, we will conduct a rapid pilot to test it in a clinical setting. Based on this pilot, we will articulate the final, validated service model and value propositions that could then be either spread/scaled, or evaluated in a larger trial.

### C. Clinical Evaluation

There are three steps involved in outlining an evaluation strategy:

#### 1) **Identify outcomes of interest (Impact)**

The evaluation design stems from the desired impacts, as identified through the lens of the **Quadruple Aim**. Quadruple Aim outcomes include the following: population health (e.g. quality of life, efficacy), per capita cost (e.g. efficiency, resource strain), and provider/patient care experience (e.g. burden, satisfaction). Equity is also considered as an overarching concept across all outcomes. We come back to the **problem definition**: what are the potential areas of impact of solving this problem?

Essential to the sustainability of a digital health solution is first identifying the payer, and second understanding the needs, interests, and outcomes of interest to the payer. The potential payer (e.g. health system, institution, provider, patient, or insurance company) should be consulted in the design of the evaluation to identify metrics that will shape the decision to purchase the solution (e.g. cost reduction). This will inform whether and how the clinical evaluation has the potential to influence the likelihood that the solution will be procured.

#### 2) **Implement the solution into a clinical environment (Feasibility)**

The evaluation is designed around the pre-selected outcomes of interest, and implemented according to the [Tool+Team+Routine] ([TTR]) heuristic. The **tool** (digital solution), **team** (technology users), **routine** (clinical model) heuristic is a service design model with essential considerations for the successful implementation of digital solutions in a clinical environment. These considerations must align with the lens of the payer to enable procurement as appropriate once the evaluation is complete (Fig 3). Thus, [TTR] allows you to develop a model in which you effectively integrate the tool into a new or existing workflow.

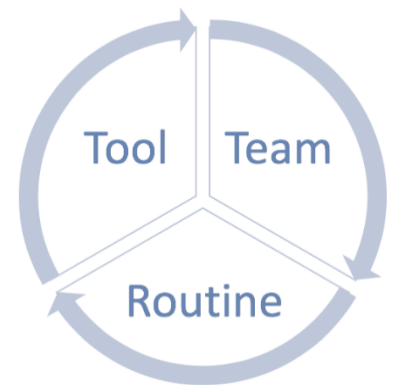


Figure 3. [Tool+Team+Routine] model.

#### 3) **Choose Your Evaluation Methodology (Impact)**

There are a number of methodologies that can be used which depend on the outcomes of interest, number of potential participants, and the [Tool+Team+Routine] heuristic. Studies generally include both quantitative evaluation and a qualitative component.

**Quantitative methodologies**

Outcomes may include efficacy, health outcomes, cost, system usage



Qualitative methodologies

Outcomes may include process, routine, experience, adoption, implementation, maintenance



## References

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