NAVIGATING THE HEALTHTECH INNOVATION CYCLE

INTRODUCTION

The journey from identifying and articulating an important unmet medical need to developing an innovative solution which becomes the standard of care is long and challenging, with most teams failing somewhere along the way. The odds of successfully navigating the journey significantly increase if teams have the experience and skills needed to anticipate and address challenges along the way. However, for most HealthTech innovators, knowing the landscape and pitfalls to plan effectively only comes from gaining experience through prior successes and/or failures – quite an inefficient process.

CIMIT believes that innovation in HealthTech is a learnable process. We have created a roadmap to help budding entrepreneurs successfully navigate the journey by learning from and building on the experiences of others. The roadmap is based on CIMIT’s HealthTech Innovation Cycle. It includes a series of well-defined milestones, each with a minimum set of deliverables in the four key dimensions required for success, clinical, market/business, regulatory, and technical.

HEALTHTECH INNOVATION CYCLE

CIMIT has termed the process of creating innovative products, procedures, and care delivery systems the “HealthTech Innovation Cycle.” As shown in Figure 1, it outlines milestones in stages from “Invention”, to “Translation”, through “Commercialization”. Representing this process as cyclical, rather than linear, highlights a key lesson learned – success is more likely by starting with clinical problems rather than pushing technology solutions and by keeping a focus on the result of improving patient care. The cycle operates at its best as a spiral, arriving at the end of each rotation at a higher standard of care, awaiting new medical insights and innovations for further enhancement.

Figure 1: HealthTech Innovation Cycle

COMMERCIALIZATION

10 Standard of Care (SoC)
The solution is recognized as the standard of care
9 Clinical Use (Use)
The solution is used successfully in day-to-day clinical practice
8 Approval & Launch (A&L)
Institutional and regulatory approval received and sales launch
7 Validation of Solution (VoS)
The solution is shown to be effective and its value to all stakeholders is validated
6 Initial Clinical Trials (ICT)
Regulated production of prototypes and collection of clinical and economic data

INVENTION

1 Need
Insights into unmet clinical needs and available solutions
2 Idea
Potential solution described to an unmet need
3 Proof of Concept (PoC)
Key component concepts validated in models and value proposition articulated
4 Proof of Feasibility (PoF)
Feasibility of whole solutions demonstrated in models and with stakeholders
5 Proof of Value (PoV)
The potential of the solution to work and create value for all stakeholders is demonstrated
DE-RISKING THE PROCESS

The technical milestones, modeled after the Department of Defense’s Technology Readiness Levels (TRLs), are modified for HealthTech innovations. In addition to the technology deliverables for each milestone, deliverables are defined for the clinical, market/business, and regulatory aspects to assist in managing risk. Examples of the types of questions addressed in the four dimensions are:

- **CLINICAL RISK**  Will the innovation be accepted and adopted in a workflow and produce real improvements in outcomes and/or lower costs?
- **MARKET/BUSINESS RISK**  Is there a significant unmet need with enough buyers willing to buy the innovation at a sustainable price?
- **REGULATORY RISK**  What claims will you need to prove and how long/how much will it cost to get approval?
- **TECHNICAL RISK**  Will the technology be protectable as well as work better and be lower cost than alternatives?

Addressing the risks in each of these dimensions in parallel as a team progresses reduces the overall risk for the project. Too often, we see teams that have progressed far down the technical path only to learn of a fundamental business, regulatory, or clinical issue that derails the project, which could have been identified early on.

DEFINING DELIVERABLES

CIMIT has developed the full matrix of deliverables for each stage and dimension. The 4x10 matrix is presented as an appendix to this summary. It defines a minimum set of deliverables expected in each cell for each dimension at each stage. The deliverables typically require significantly more work to complete as the stages progress. Coupled with a time-stamp for each deliverable, the rate of progress can be measured. This provides an indication if a project is becoming bogged down and, in aggregate, how one portfolio compares to another. CIMIT’s CoLab tool captures these parameters to enable teams to map their progress.

MEASURING AND MONITORING PROGRESS

A team’s progress can be measured in a matrix format with, as outlined in Figure 2, progress in each dimension measured by the deliverables achieved. The approach is valuable as a visual diagnostic. The example below immediately shows that progress in one dimension proceeds in advance of the others. In addition to providing guidance for what work needs to be done now to de-risk the entire project by bringing progress in each dimension to the same stage, it provides a roadmap to plan future deliverables.

---

Please contact CIMIT with questions or suggestions for how to better navigate the HealthTech Innovation Cycle.
<table>
<thead>
<tr>
<th>Level/ Name</th>
<th>Overall Description</th>
<th>Innovation Maturity Level Descriptors (Deliverables)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clinical</td>
<td>Market/Business</td>
</tr>
<tr>
<td>1. Need</td>
<td>Insights into unmet clinical needs and available solutions</td>
<td>Unmet need is articulated based on clinical experience</td>
</tr>
<tr>
<td>2. Idea</td>
<td>Potential solution described to unmet need</td>
<td>Clinical workflow scenario description</td>
</tr>
<tr>
<td></td>
<td>Key component concepts validated in models and value proposition articulated</td>
<td>Positive feedback from clinicians in other settings (&gt;5)</td>
</tr>
<tr>
<td>3. Proof of Concept (PoC)</td>
<td>Feasibility of whole solution demonstrated in models and in feedback from stakeholders</td>
<td>Positive feedback from (Total ≥ 20) other clinicians in target settings</td>
</tr>
<tr>
<td></td>
<td>The potential of the solution to work and create value for all stakeholders is demonstrated (initial commercial investment)</td>
<td>Positive feedback from other clinicians (≥ 50) and KOLs</td>
</tr>
<tr>
<td></td>
<td>Regulated production of prototypes and collection of clinical and economic data</td>
<td>Conduct phase 0 and/or 1 clinical trial(s) to determine the safety and effectiveness of the solution</td>
</tr>
<tr>
<td>5. Proof of Value (PoV)</td>
<td>The solution is shown to be effective and its value to all stakeholders is validated</td>
<td>Clinical efficacy trials (e.g., phase 2 and 3), and/or expanded clinical safety trials</td>
</tr>
<tr>
<td></td>
<td>Institutional and regulatory approval received and sales launch</td>
<td>Specialty medical groups review</td>
</tr>
<tr>
<td>7. Validation of Solution (VoS)</td>
<td>The solution is used successfully in day-to-day clinical practice</td>
<td>Included in practice guidelines</td>
</tr>
<tr>
<td></td>
<td>The solution is recognized as the standard of care</td>
<td>Recommended practice by medical specialty</td>
</tr>
</tbody>
</table>