Navigating the Healthcare Innovation Cycle

CIMIT
Consortia for Improving Medicine with Innovation & Technology

Introduction:

CIMIT's 20+ years of experience in facilitating more than 600 projects is that innovation in Healthcare is a learnable, teachable process, which it has termed the "Healthcare Innovation Cycle". By following the process, teams can put the experiences of others in navigating the journey of healthcare innovation into action and help avoid preventable mistakes that can derail even the most promising of ideas. The result is improved speed and chances that promising innovations actually reach patients and improve care.

Healthcare Innovation Cycle:

The Healthcare Innovation Cycle, Figure 1, parallels the US Department of Defense's well-established Technology Readiness Level (TRL) framework. It establishes a sequence of healthcare specific milestones that creates a roadmap to guide teams as they navigate the complex journey from an unmet clinical need to becoming the standard of care. However, it differs from the TRL framework in three important ways:

First, it represents the process as a cycle rather than being linear and starting with the technology. This highlights a key lesson learned: to improve the chances of success, start with unmet clinical needs/problems rather than technology solutions and always keep a focus on improving patient care and not become enamored with improving the technology. When done correctly, the cycle operates 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: Healthcare Innovation Cycle

Second, TRL's stop at 9, with the solution being used in practice and a 10th was added for healthcare. In healthcare, considerable work is needed to disseminate innovations so that they are widely available. So, Healthcare Innovation Cycle has a 10th milestone: "Standard of Care".

Third, de-risking healthcare projects requires constantly balancing the perspectives from four key domains critical to creating a successful healthcare solution: clinical, market/business, regulatory, as well as technical. The TRL framework only focuses on the technology – why create a new product with nifty new technology that nobody wants to use or will by, and even if they wanted to, is not approved for use? We have found that proceeding in a balanced manner greatly assists teams in managing risks. Risks can never be eliminated, but they need to be understood and addressed as soon as possible so as not to reduce the chances of following a path that leads to a dead-end.

De-Risking

Examples of the types of questions in the four domains that are addressed at each milestone are outlined below, with increasing evidence expected as the solution matures:

- 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?

Defining Deliverables

CIMIT's experience is that while each is journey is different, just as each ascent a mountain climber makes on a new peak is different, the underlying disciplines applied are the same. To capture the experiences, it has defined a core set of deliverables for each milestone and domain that should be finished before advancing too far into the next milestone.

Attached is a table that has the core set of deliverables in each "cell" of the 4 domains by 10 milestones matrix for HealthTech solutions (in the EU). Check-off each Deliverable that is complete and use the Deliverables to plan your work – which in some cases will mean filling in gaps

Guidance and Impact Tracking System (GAITS)

To assist teams and portfolio managers utilize the Healthcare Innovation Cycle, CIMIT developed and is piloting a secure, on-line platform: The GAITS platform. It provides descriptions of the deliverables at the intersection of each milestone and domain along with resources to help teams complete them. It is configured to reflect the differences in fields (e.g. HealthTech, Pharma, Health IT, etc.) and expectations of unique customers. (e.g. Military) The resources (e.g. descriptions, videos, templates, examples, etc.) are curated, peer-rated, and open source to present teams with the ones that are most effective in helping complete each deliverable.

The platform will also provide tracking, planning, reviewing, and reporting functions. A pilot is currently ongoing, and the platform is expected to be commercially available in the fall of 2018.

Contact:

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Healthcare Innovation Cycle – HealthTech Deliverables Matrix (EU)

Solution Name: _____ Date: _____

Milestone Name	Overall Description	Clinical	Market/Business	Regulatory/ Approvals	Technology
1) Need	Insights into unmet clinical needs and available solutions	☐ Unmet needs defined ☐ Disease state characterized	☐ Needs screening & selection ☐ Existing solutions characterized	NA	NA
2) Idea	Potential solutions to unmet need developed and evaluated	☐ Clinical workflow description ☐ Updated need description ☐ Feedback from >5 clinicians	☐ Competitive landscape ☐ Envisioned Value Proposition	☐ Medical device intended use ☐ Equivalent devices identified	☐ Paper Prototype ☐ Hypothesis & experimental design ☐ Idea screening & selection
3) Proof of Concept (PoC)	Key component concepts validated in models and value proposition articulated	☐ Feedback from clinicians in >5 settings ☐ Updated need description and workflow	☐ Competing solutions characterization ☐ Preliminary Value Proposition ☐ Path to Payment plan ☐ Stakeholder Map	☐ Preliminary classification ☐ Preliminary intended use ☐ Preliminary regulatory pathway	☐ PoC prototypes ☐ Demonstration results ☐ Institutional IP disclosure
4) Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	☐ Feedback from clinicians in >20 settings ☐ Updated need & workflow descriptions	☐ Feedback from >5 economic buyers ☐ Impact Plan (draft business plan) ☐ Advisory Board	☐ Draft Essential Requirements Checklist ☐ Draft Instructions for use ☐ Institutional approval request(s)	☐ “Works Like” & “Looks Like” prototypes ☐ Freedom to operate review ☐ Provisional IP filing ☐ Killer Experiment

Healthcare Innovation Cycle – HealthTech Deliverables Matrix (EU)

Milestone Name	Overall Description	Clinical	Market/Business	Regulatory/ Approvals	Technology
5) Proof of Value (PoV)	The potential of the solution to work and create value for all stakeholders is demonstrated (Initial commercial investment)	☐ Feedback from >100 clinicians and KOLs ☐ Animal/First-in-Man experiments ☐ Peer reviewed publication(s) ☐ Scientific Advisory Board	☐ Investor ready business plan ☐ Feedback from >20 economic buyers ☐ Key management team identified ☐ Initial seed investment	☐ Application form to national competent authority ☐ Data requirements ☐ Clinical Investigation approval(s)	☐ "Works Like/Looks Like" prototypes ☐ BOM, manufacturing plan, and costing ☐ Full IP application ☐ Killer technical experiment
6) Initial Clinical Trials (ICT)	Regulated production of prototypes and collection of clinical and economic data	☐ Conduct Phase 0 and/or 1 clinical trial(s) ☐ Peer reviewed publication(s)	☐ Economic data ☐ Feedback from >50 economic buyers ☐ 1st Institutional Investment	☐ Data requirements confirmation ☐ Pre-submission	☐ Manufacture GMP-compliant pilot lots.
7) Validation of Solution (VoS)	The solution is shown to be effective and its value to all stakeholders is validated	☐ Clinical efficacy trials ☐ Peer reviewed publication(s)	☐ Purchasing intent from >10 buyers ☐ 2nd round of institutional investment	☐ Complete Technical File ☐ Technical File submission to Notified Body (CE Mark)	☐ GMP Process Planning
8) Approval & Launch (A&L)	Institutional and regulatory approval received, and sales launched	☐ Training materials & support established ☐ Peer reviewed publication(s)	☐ Initial sales	☐ Registration and Listing (CE mark) ☐ CMS Coverage & CPT Code Determination	☐ Finalized GMP process

Healthcare Innovation Cycle – HealthTech Deliverables Matrix (EU)

Milestone Name	Overall Description	Clinical	Market/Business	Regulatory/ Approvals	Technology
9) Clinical Use (Use)	The solution is used successfully in day-day clinical practice	☐ Included in local practice guidelines ☐ Peer reviewed publication(s)	☐ Profitable sales	☐ Monitoring and Inspections	☐ Patents issued ☐ Improvement plan
10) Standard of Care (SoC)	The solution is recognized as the Standard of Care.	☐ Recommended practice by medical specialty	☐ Dominant market share	NA	NA