NAVIGATING THE HEALTHTECH INNOVATION CYCLE

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Consortia for Improving Medicine with Innovation & Technology

INTRODUCTION

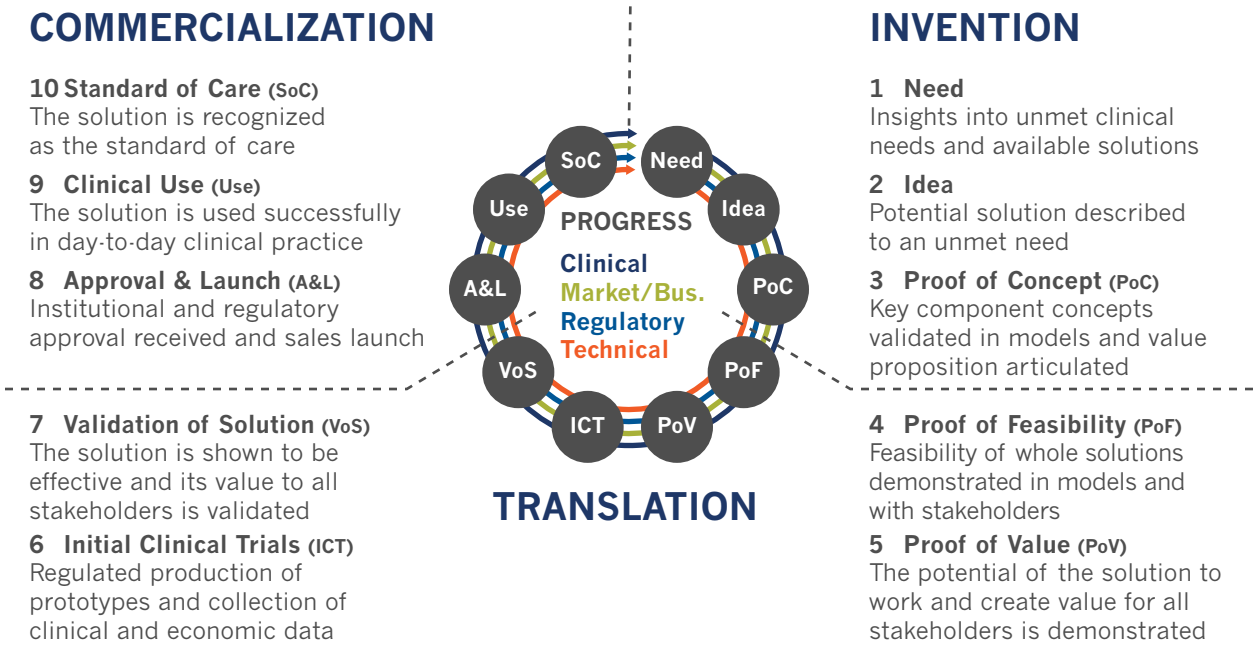
The journey from identifying and articulating an important unmet medical need to developing an innovative solution which becomes the standard of care is long and challenging, with most teams failing somewhere along the way. The odds of successfully navigating the journey significantly increase if teams 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



NAVIGATING THE HEALTHTECH INNOVATION CYCLE (CONT.)

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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

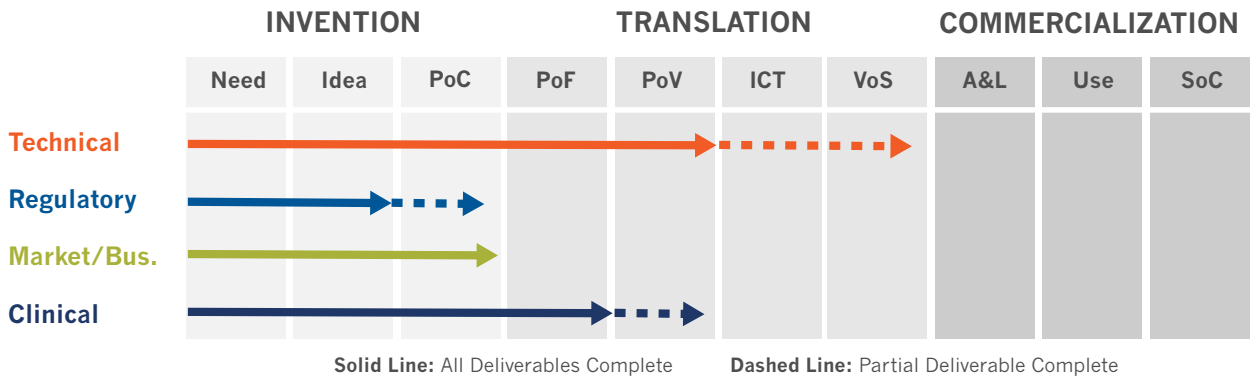
CIMIT has developed the full matrix of deliverables for each stage and dimension. The 4x10 matrix is presented as an appendix to this summary. It defines a minimum set of deliverables expected in each cell for each dimension at each stage.

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 aggerate, 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.

Figure 2: HealthTech Innovation Cycle Progress Matrix for Example Project



Please contact CIMIT with questions or suggestions for how to better navigate the HealthTech Innovation Cycle.

Appendix 1: HealthTech Innovation Readiness (HIR) Level Deliverables

Level/ Name	Overall Description	Innovation Maturity Level Descriptors (Deliverables)			
		Clinical	Market/Business	Technology	Regulatory
1. Need	Insights into unmet clinical needs and available solutions	Unmet need is articulated based on clinical experience	Deficiency in existing solutions identified	Available solutions identified and new technologies searched	NA
2. Idea	Potential solution described to unmet need	Clinical workflow scenario description	Competitive landscape and preliminary reimbursement review	"Paper Prototype" and initial institutional "Idea" (IP) disclosure and review Hypothesis experimental designs for addressing the technical issues of key components	Preliminary solution classification and predicates identified
3. Proof of Concept (PoC)	Key component concepts validated in models and value proposition articulated	Positive feedback from clinicians in other settings (>5)	Preliminary "Value Proposition" and "Path to Payment" plan	Experiments validate key components hypotheses. (In vivo, in silica, and maybe in vitro) Refined institutional IP disclosure	Solution classification and preliminary regulatory pathway defined
4. Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	Positive feedback from (Total ≥ 20) other clinicians in target settings	Positive feedback from economic buyers (>5) Preliminary business model and plan (including reimbursement path)	"Looks Like" and "Works Like" prototypes FTO review and provisional IP filing Killer technical experiment (e.g. initiation of animal model development for desired indication)	Submission pathway defined IRB approvals
5. Proof of Value (PoV)	The potential of the solution to work and create value for all stakeholders is demonstrated (initial commercial investment)	Positive feedback from other clinicians (≥ 50) and KOLs Animal/first in man experiments Peer reviewed publication(s)	Investor ready business plan Positive feedback from economic buyers (≥50) Key management team identified and seed investment (NewCo or project)	"Works Like, Looks Like" prototypes of MVP with product IFU Manufacturing plan and costing Full IP application Killer technical experiment (e.g. non-GLP animal studies for regulatory filing)	Submission data package defined
6. Initial Clinical Trails (ICT)	Regulated production of prototypes and collection of clinical and economic data	Conduct phase 0 and/or 1 clinical trial(s) to determine the safety and effectiveness of the solution	Collection of economic data compared to SoC (e.g. validating beachhead market) 1st round of institutional investment	Manufacture GMP-compliant pilot lots	Preliminary FDA guidance (not a meeting necessarily) and data package assembled
7. Validation of Solution (VoS)	The solution is shown to be effective and its value to all stakeholders is validated	Clinical efficacy trials (e.g., phase 2 and 3), and/or expanded clinical safety trials Training materials established	Purchasing intent from lead users 2nd round of institutional investment	Initiation of GMP process validation	Submission
8. Approval & Launch (A&L)	Institutional and regulatory approval received and sales launch	Specialty medical groups review	Initial sales Reimbursement code	Finalized GMP manufacturing process	Registration and listing
9. Clinical Use (Use)	The solution is used successfully in day-to-day clinical practice	Included in practice guidelines	Profitable sales	US IP issued; improvements under development	Monitoring/ inspections
10. Standard of Care (SoC)	The solution is recognized as the standard of care	Recommended practice by medical specialty	Dominant market share	Int'l IP issued; next generation under development	NA