

The CIMIT Healthcare Innovation Cycle – HealthTech Deliverables Checklist

For more information on Deliverables see: <https://www.gaits.org/public-plan-track>

Solution Name: _____ Not Started In Progress Completed Date: _____

Milestone Name	Overall Description	Clinical	Market/Business	Regulatory/ Approvals	Technology
1) Need	Insights into unmet clinical needs and available solutions	<input type="checkbox"/> Unmet needs <input type="checkbox"/> Disease state characterization	<input type="checkbox"/> Needs screening & selection <input type="checkbox"/> Existing solutions characterized <input type="checkbox"/> Reimbursement Familiarization	<input type="checkbox"/> Regulation Familiarization	<input type="checkbox"/> State of the Art Summary
2) Idea	Potential solutions to unmet need developed, evaluated, and selected	<input type="checkbox"/> Clinical workflow description <input type="checkbox"/> Updated need statement <input type="checkbox"/> Feedback from >5 clinicians	<input type="checkbox"/> Competitive landscape <input type="checkbox"/> Envisioned Value Proposition <input type="checkbox"/> Key stakeholders identified	<input type="checkbox"/> Medical device determination <input type="checkbox"/> Comparables/predicates identified	<input type="checkbox"/> Idea screening & selection <input type="checkbox"/> Paper Prototype <input type="checkbox"/> Hypothesis & experimental design
3) Proof of Concept (PoC)	Key component concepts validated in models and value proposition tested	<input type="checkbox"/> Feedback from clinicians in >5 settings <input type="checkbox"/> Updated need description and workflow	<input type="checkbox"/> Competing solutions characterization <input type="checkbox"/> Preliminary Value Proposition <input type="checkbox"/> Path to Payment plan <input type="checkbox"/> Stakeholder Map <input type="checkbox"/> Founders' Agreement	<input type="checkbox"/> Preliminary solution classification <input type="checkbox"/> Preliminary intended / indications for use <input type="checkbox"/> Preliminary regulatory pathway	<input type="checkbox"/> PoC prototypes <input type="checkbox"/> Demonstration results <input type="checkbox"/> Institutional IP disclosure
4) Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	<input type="checkbox"/> Feedback from clinicians in >20 settings <input type="checkbox"/> Updated need & workflow descriptions	<input type="checkbox"/> Feedback from >5 economic buyers <input type="checkbox"/> Preliminary Business Model <input type="checkbox"/> Advisory Board <input type="checkbox"/> Incorporation	<input type="checkbox"/> Draft Essential Requirements Checklist <input type="checkbox"/> Draft Instructions for Use (IFUs) <input type="checkbox"/> Institutional approval request(s) (IRBs)	<input type="checkbox"/> Product Requirements Doc (PRD) <input type="checkbox"/> "Works Like" prototypes & results <input type="checkbox"/> "Looks Like" prototypes <input type="checkbox"/> Provisional IP filing & FTO review

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5) Proof of Value (PoV)	The potential of the solution to work and create value for all stakeholders is demonstrated	<input type="checkbox"/> Feedback from >100 clinicians and KOLs <input type="checkbox"/> Animal/ First-in-or-with man exp's <input type="checkbox"/> Peer reviewed publication(s) <input type="checkbox"/> Scientific Advisory Board	<input type="checkbox"/> Investor ready business plan <input type="checkbox"/> Feedback from >20 economic buyers <input type="checkbox"/> Key management team identified <input type="checkbox"/> Initial seed investment	<input type="checkbox"/> Essential requirements checklist <input type="checkbox"/> Clinical investigation approval(s) (IRBs)	<input type="checkbox"/> "Works Like/Looks Like" prototypes <input type="checkbox"/> Specification & experimental results <input type="checkbox"/> Preliminary BOM, manufacturing plan, and costing <input type="checkbox"/> Full IP application
6) Initial Clinical Trials (ICT)	Regulated production of prototypes and collection of clinical and economic data	<input type="checkbox"/> Conduct Phase 0 and/or 1 clinical trial(s) <input type="checkbox"/> Peer reviewed publication(s)	<input type="checkbox"/> Economic data <input type="checkbox"/> Feedback from >50 economic buyers <input type="checkbox"/> 1st Institutional Investment	<input type="checkbox"/> Data requirements confirmation <input type="checkbox"/> Pre-submission	<input type="checkbox"/> Manufacture GMP-compliant pilot lots. <input type="checkbox"/> Updated specification & experimental validation
7) Validation of Solution (VoS)	Solution is shown to be effective and its value to all stakeholders validated	<input type="checkbox"/> Clinical efficacy trials <input type="checkbox"/> Peer reviewed publication(s)	<input type="checkbox"/> Purchasing intent from >10 buyers <input type="checkbox"/> 2nd round of institutional investment	<input type="checkbox"/> Complete Technical File <input type="checkbox"/> Submission to Authorizing Body	<input type="checkbox"/> GMP process planning <input type="checkbox"/> Updated specification & experimental validation
8) Approval & Launch (A&L)	Institutional and regulatory approval received, and sales launched	<input type="checkbox"/> Training materials & support established <input type="checkbox"/> Peer reviewed publication(s)	<input type="checkbox"/> Initial sales	<input type="checkbox"/> Registration and Listing (CE mark) <input type="checkbox"/> CMS Coverage & CPT Code Determination	<input type="checkbox"/> Finalized GMP process <input type="checkbox"/> Updated specification & experimental validation

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9) Clinical Use (Use)	The solution is used successfully in day-day clinical practice	<input type="checkbox"/> Included in local practice guidelines <input type="checkbox"/> Peer reviewed publication(s)	<input type="checkbox"/> Profitable sales	<input type="checkbox"/> Monitoring and Inspections	<input type="checkbox"/> Patents issued <input type="checkbox"/> Improvement plan
10) Standard of Care (SoC)	The solution is recognized as the Standard of Care.	<input type="checkbox"/> Recommended practice by medical specialty	<input type="checkbox"/> Dominant market share	NA	NA