The CIMIT Healthcare Innovation Cycle – HealthTech Deliverables Checklist

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 ☐ Disease state characterization	☐ Needs screening & selection ☐ Existing solutions characterized ☐ Reimbursement Familiarization	☐ Regulation Familiarization	☐ State of the Art Summary
2) Idea	Potential solutions to unmet need developed, evaluated, and selected	☐ Clinical workflow description ☐ Updated need statement ☐ Feedback from >5 clinicians	☐ Competitive landscape ☐ Envisioned Value Proposition ☐ Key stakeholders identified	☐ Medical device determination ☐ Comparables/ predicates identified	☐ Idea screening & selection ☐ Paper Prototype ☐ Hypothesis & experimental design
3) Proof of Concept (PoC)	Key component concepts validated in models and value proposition tested	☐ Feedback from clinicians in >5 settings ☐ Updated need description and workflow	☐ Competing solutions characterization ☐ Preliminary Value Proposition ☐ Path to Payment plan ☐ Stakeholder Map	☐ Preliminary solution classification ☐ Preliminary intended / indications for 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 ☐ Preliminary Business Model ☐ Advisory Board	☐ Draft Essential Requirements Checklist ☐ Draft Instructions for Use (IFUs) ☐ Institutional approval request(s) (IRBs)	☐ Product Requirements Doc (PRD) ☐ "Works Like" prototypes & results ☐ "Looks Like" prototypes ☐ 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	☐ Feedback from >100 clinicians and KOLs ☐ Animal/ First-in-or-with man exp's ☐ Peer reviewed publication(s) ☐ Scientific Advisory Board	☐ Investor ready business plan ☐ Feedback from >20 economic buyers ☐ Key management team identified ☐ Initial seed investment	☐ Essential requirements checklist ☐ Clinical investigation approval(s) (IRBs)	☐ "Works Like/Looks Like" prototypes ☐ Specification & experimental results ☐ Preliminary BOM, manufacturing plan, and costing ☐ Full IP application
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. ☐ Updated specification & experimental validation
7) Validation of Solution (VoS)	Solution is shown to be effective and its value to all stakeholders validated	☐ Clinical efficacy trials ☐ Peer reviewed publication(s)	☐ Purchasing intent from >10 buyers ☐ 2nd round of institutional investment	☐ Complete Technical File ☐ Submission to Authorizing Body	☐ GMP process planning ☐ Updated specification & experimental validation
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 ☐ Updated specification & experimental validation

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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

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