

HealthTech Milestones & Deliverables Matrix

Solution Name: _____

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 defined <input type="checkbox"/> Disease state characterized <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> Needs screening & selection <input type="checkbox"/> Existing solutions characterized <input type="checkbox"/> Flag/Comment	NA	NA
2) Idea	Potential solutions to unmet need developed and evaluated	<input type="checkbox"/> Clinical workflow description <input type="checkbox"/> Updated need description <input type="checkbox"/> Feedback from >5 clinicians <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> Competitive landscape <input type="checkbox"/> Envisioned Value Proposition <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> Medical device determination <input type="checkbox"/> Comparables/ Predicates <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> Paper Prototype <input type="checkbox"/> Hypothesis & experimental design <input type="checkbox"/> Idea screening & selection <input type="checkbox"/> Flag/Comment
3) Proof of Concept (PoC)	Key component concepts validated in models and value proposition articulated	<input type="checkbox"/> Feedback from clinicians in >5 settings <input type="checkbox"/> Updated need description and workflow <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> Competing solutions characterization <input type="checkbox"/> Preliminary Value Proposition <input type="checkbox"/> Path to Payment plan <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> Prelim. Sol'n classification <input type="checkbox"/> Preliminary indications for/ intended use <input type="checkbox"/> Prelim. regl'y pathway <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> PoC prototypes <input type="checkbox"/> Demonstration results <input type="checkbox"/> Institutional IP disclosure <input type="checkbox"/> Flag/Comment
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"/> Flag/Comment	<input type="checkbox"/> Feedback from >5 economic buyers <input type="checkbox"/> Impact Plan <input type="checkbox"/> Advisory Board <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> Draft Essential Req's Table <input type="checkbox"/> IFU <input type="checkbox"/> IRB Submission(s) <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> "Works Like" & "Looks Like" prototypes <input type="checkbox"/> FTO review <input type="checkbox"/> Provisional IP filing <input type="checkbox"/> Killer Experiment <input type="checkbox"/> Flag/Comment

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5) Proof of Value (PoV)	The potential of the solution to work and create value for all stakeholders is demonstrated (Initial commercial investment)	<input type="checkbox"/> Feedback from >100 clinicians and KOLs <input type="checkbox"/> Animal/First-in-Man experiments <input type="checkbox"/> Peer reviewed publication(s) <input type="checkbox"/> Scientific Advisory Board <input type="checkbox"/> Flag/Comment	<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"/> Flag/Comment	<input type="checkbox"/> Data requirements <input type="checkbox"/> IRB Approval(s) <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> "Works Like/Looks Like" prototypes <input type="checkbox"/> BOM, manufacturing plan, and costing <input type="checkbox"/> Full IP application <input type="checkbox"/> Killer technical experiment <input type="checkbox"/> Flag/Comment
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"/> Flag/Comment	<input type="checkbox"/> Economic data <input type="checkbox"/> Feedback from >50 economic buyers <input type="checkbox"/> 1st Institutional Investment <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> Data requirements confirmation <input type="checkbox"/> Pre-submission <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> Manufacture GMP-compliant pilot lots. <input type="checkbox"/> Flag/Comment
7) Validation of Solution (VoS)	The solution is shown to be effective and its value to all stakeholders is validated	<input type="checkbox"/> Clinical efficacy trials <input type="checkbox"/> Peer reviewed publication(s) <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> Purchasing intent from >10 buyers <input type="checkbox"/> 2nd round of institutional investment <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> Complete submission package <input type="checkbox"/> Regulatory submission <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> GMP Process Planning <input type="checkbox"/> Flag/Comment
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"/> Flag/Comment	<input type="checkbox"/> Initial sales <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> Registration and Listing <input type="checkbox"/> CMS Coverage & CPT Code Determination <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> Finalized GMP process <input type="checkbox"/> Flag/Comment

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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"/> Flag/Comment	<input type="checkbox"/> Profitable sales <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> Monitoring and Inspections <input type="checkbox"/> Flag/Comment	<input type="checkbox"/> Patents issued <input type="checkbox"/> Improvement plan <input type="checkbox"/> Flag/Comment
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"/> Flag/Comment	<input type="checkbox"/> Dominant market share <input type="checkbox"/> Flag/Comment	NA	NA